CHEMICAL SAFETY REPORT

Substance Name: 1-phenoxypropan-2-ol

EC Number: 212-222-7

CAS Number: 770-35-4

Registrant's Identity: DOW BENELUX B. V. - OR1

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

For propylene glycol phenyl ether the following risk management measures are recommended:

Recommended Exposure Levels for workers

- The registrant had established a DNEL of 25.7 mg/m3 for worker long-term systemic inhalation exposure.
- The DNEL for worker long-term systemic exposure via the dermal route is 42 mg/kg bw/day and 21 mg/kg bw/day for consumers.
- The DNEL for consumer exposure via the oral route is 3.65 mg/kg bw/day.
- Detailed information about the safe handling and use of this substance for various exposure scenarios is described in the extended Safety Data Sheet.

Classification and Labelling

Propylene glycol phenyl ether is classified as eye irritant with R36 and H319 according to Annex I of EU Directive 67/548 (Dangerous Substance Directive) and according to the GSH/CLP, respectively.

Recommended Exposure Levels for the environment

The registrant has established the following PNECs:

- PNEC aqua (freshwater): 0.1 mg/l
- PNEC aqua (marine water): 0.01 mg/l
- PNEC aqua (intermittent releases): 1 mg/l
- PNEC sediment (freshwater): 0.38 mg/kg sediment d.w.
- PNEC sediment (marine water): 0.038 mg/kg sediment d.w.
- PNEC soil: 0.02 mg/kg soil d.w.
- PNEC stp: 10 mg/l

For further risk management measures to control worker, consumer and environmental exposure, please refer to the exposure scenarios described in part B, chapter 9 of this document.

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

The registrant declares that the above risk management measures are implemented at the registrant's use sites in the EU. Employees are frequently informed about hazards properties of the substances they work with.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

The registrant declares that the above risk management measures are communicated to distributors and direct customers by means of the extended Safety Data Sheet and other appropriate literature. The registrant's internal systems enable to send the up-dated Safety Data Sheets to customers when significant changes are made in these documents.

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

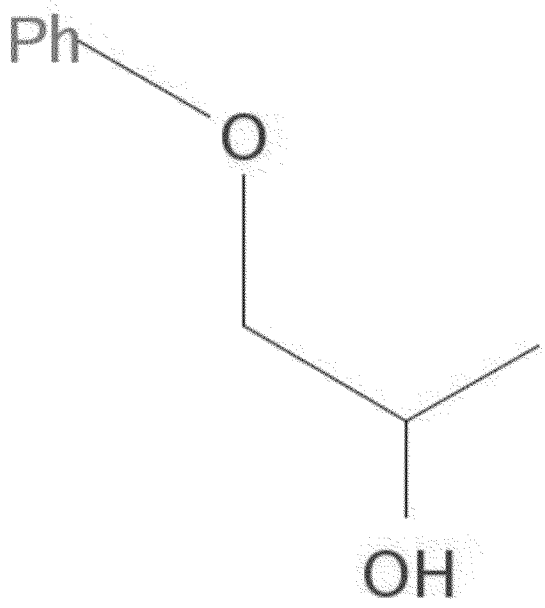
The substance **1-phenoxypropan-2-ol** is a mono constituent substance (origin: organic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: propylene glycol phenyl ether.

Table 1. Substance identity

EC number:	212-222-7
EC name:	1-phenoxypropan-2-ol
CAS number (EC inventory):	770-35-4
CAS name:	2-Propanol, 1-phenoxy-
IUPAC name:	1-phenoxypropan-2-ol
Molecular formula:	C9H12O2
Molecular weight range:	152.19

Structural formula:



Remarks:

1.2. Composition of the substance

Name: Propylene glycol phenyl ether

Degree of purity: >= 80.0 — <= 100.0 % (w/w)

Table 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
1-phenoxypropan-2-ol EC no.: 212-222-7	ca. 99.8 % (w/w)	> 99.0 — <= 100.0 % (w/w)	

Table 3. Impurities

Impurity	Typical concentration	Concentration range	Remarks
Unspecified impurities, each < 0.1%	ca. 0.2 % (w/w)	>= 0.0 — < 1.0 % (w/w)	

1.3. Physico-chemical properties

Table 4. Overview of physico-chemical properties

Property	Results	Value used for CSA / Discussion
Physical state at 20°C and 1013 hPa	Propylene glycol phenyl ether (1-phenoxypropan-2-ol) is a clear and colourless liquid.	**Value used for CSA:** liquid
Melting / freezing point	The melting point of phenoxypropanol is 11 °C.	**Value used for CSA:** 11 °C at 1013 hPa
Boiling point	The boiling point of propylene glycol phenyl ether (1-phenoxypropan-2-ol) is 241.2 °C at 101.3 kPa.	**Value used for CSA:** 241.2 °C at 1013 hPa
Relative density	The relative density of 1-phenoxypropan-2-ol is 1.06 at 20 °C.	**Value used for CSA:** 1.06 at 20°C
Vapour pressure	The vapour pressure of 1-phenoxypropan-2-ol is 0.01 hPa at 20 °C.	**Value used for CSA:** 0.01 hPa at 20 °C
Surface tension	The surface tension of a solution of 1-phenoxypropan-2-ol at a concentration of 1 g/l in water at 20 °C is 67.8 mN/n. Therefore, 1-phenoxypropan-2-ol is considered to be not surface active.	**Value used for CSA:** 67.8 mN/m at 20°C and 1000 mg/L
Water solubility	The water solubility of propylene glycol phenyl ether (mixture of 85 % 1-phenoxy-2-propanol, 15 % 2-phenoxy-1-propanol) is 15.1 g/l at 20 °C and pH of 7.	**Value used for CSA:** 15.1 g/L at 20 °C
Partition coefficient n-octanol/water (log value)	The partition coefficient of 1-phenoxypropan-2-ol is log Pow = 1.41 at 24.1 °C and pH of 7.	**Value used for CSA:** Log Kow (Pow): 1.41 at 24.1 °C
Flash point	The flash point of 1-phenoxypropan-2-ol is 115 °C (239 °F) at atmospheric pressure.	**Value used for CSA:** 115 °C at 1013 hPa
Flammability	1-Phenoxypropan-2-ol (propylene glycol phenyl ether) is not classified for flammability according to EU criteria.	**Value used for CSA:** non flammable

Explosive properties	1-Phenoxypropan-2-ol (propylene glycol phenyl ether) does not contain chemically unstable or highly energetic groups like those mentioned in table R.7.1-28 (ECHA Guidance, 2008). Therefore the substance is determined to be not explosive.	**Value used for CSA:** non explosive
Self-ignition temperature	The autoignition temperature of propylene glycol phenyl ether is 480 °C.	**Value used for CSA:** 480 °C at 1013 hPa
Oxidising properties	1-Phenoxypropan-2-ol (propylene glycol methyl ether) is not an oxidizing substance according to the ECHA guidance "Guidance on information requirements and chemical safety assessment, Chapter R.7a: Endpoint specific guidance, Mai 2008). 1-Phenoxypropan-2-ol (propylene glycol methyl ether) does not contain chemical groups associated with oxidising properties. With the absence of structural alerts testing is not necessary.	**Value used for CSA:** Oxidising: no In accordance with column 2 of REACH Annex VII, the study does not need to be conducted if the substance is incapable or reacting exothermically with combustible materials. 1-Phenoxypropan-2-ol (propylene glycol phenyl ether) is a saturated glycol ether with no functional and chemical groups associated with oxidising properties. 1-Phenoxypropan-2-ol (propylene glycol phenyl ether) has no oxidising character. With the absence of structural alerts, classification for oxidizing properties is not required.
Granulometry	Propylene glycol phenyl ether is a liquid under normal conditions and is marketed and used in a non solid or non granular form. According to column 2 of Annex VII of REACH, this study does not need to be conducted.	
Stability in organic solvents and identity of relevant degradation products	1-Phenoxypropan-2-ol (propylene glycol methyl ether) is known to be stable in many common organic solvents. In accordance with column 1 of REACH Annex IX, the stability in organic solvents study does not need to be conducted as the stability of the substance is not considered as critical.	
Dissociation constant	Examination of the chemical structure of 1-phenoxypropan-2-ol (propylene glycol methyl ether) shows that there is no functional group that could dissociate. The substance does not contain both, acidic or basic functional groups. 1-Phenoxypropan-2-ol (propylene glycol methyl ether) is not an ionisable organic substance and as non-ionisable ether-alcohol will tend not to dissociate in water under normal environmental conditions. Hence, according to column 2 of Annex IX of REACH this study does not need to be conducted.	
Viscosity	The viscosity of 1-phenoxypropan-2-ol is 34 mP*s at 20 °C and 22.7 mPa*s (cP) at 25 °C.	**Value used for CSA:** Viscosity at 20°C: 34 mPa · s (dynamic)

Data waiving

Information requirement: Explosive properties

Reason: other justification

Justification: Propylene glycol phenyl ether does not contain chemically unstable or highly energetic groups like those mentioned in table R.7.1-28 (ECHA Guidance, 2008). Therefore the substance is determined to be not explosive.

Information requirement: Oxidising properties

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the study does not need to be conducted if the substance is incapable or reacting exothermically with combustible materials. 1-Phenoxypropan-2 -ol (propylene glycol phenyl ether) is a saturated glycol ether with no functional and chemical groups associated with oxidising properties. 1-Phenoxypropan-2-ol (propylene glycol phenyl ether) has no oxidising character. With the absence of structural alerts, classification for oxidizing properties is not required.

Information requirement: Granulometry

Reason: study technically not feasible

Justification: Propylene glycol phenyl ether is a liquid under normal conditions and is marketed and used in a non solid or non granular form. According to column 2 of Annex VII of REACH, this study does not need to be conducted.

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: other justification

Justification: 1-Phenoxypropan-2-ol (propylene glycol methyl ether) is known to be stable in many common organic solvents. In accordance with column 1 of REACH Annex IX, the stability in organic solvents study does not need to be conducted as the stability of the substance is not considered as critical.

Information requirement: Dissociation constant

Reason: study scientifically unjustified

Justification: Examination of the chemical structure of 1-phenoxyp ropan-2-ol (propylene glycol methyl ether) shows that there is no functional group that could dissociate. The substance does not contain both, acidic or basic functional groups. 1-Phenoxypropan- 2-ol (propylene glycol methyl ether) is not an ionisable organic substance and as non-ionisable ether-alcoho l will tend not to dissociate in water under normal environmental conditions. Hence, according to column 2 of Annex IX of REACH this study does not need to be conducted.

Discussion of physico-chemical properties

It has been concluded that the test substance does not need to be classified according to DSD or GSH based on the evaluation of all available physical and chemical properties.

2. MANUFACTURE AND USES

Quantities

Table 5. Overview of quantities (in tonnes/year)

Year	Total tonnage	Own use	Used for article	Used as intermediate under strictly controlled conditions	Used for research purposes
2010	Manufactured: 0.0 Imported: 1700.0				

2.1. Manufacture

Manufacturing process

Propylene glycol phenyl ether is manufactured outside the EU in closed, continuous equipment by the reaction of propylene oxide with phenol. The reactor effluent consists of excess phenol, the monopropylene glycol phenyl ether and higher propylene glycol phenyl ether oligomer by-products. Product purification consists of a series of distillation columns to remove the excess phenol and fractionation of propylene glycol phenyl ether from the higher oligomers. Propylene glycol phenyl ether is obtained a high purity, clear and colorless liquid.

2.2. Identified uses

Table 6. Uses by workers in industrial settings

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	1	Industrial use a chemical intermediate	as such (substance itself)	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 15: Use as laboratory reagent **Environmental release category (ERC):** ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Subsequent service life relevant for that use?:** no
	2	Industrial use as a process solvent	as such (substance itself)	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 15: Use as laboratory reagent **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Subsequent service life relevant for that use?:** no
	3	Distribution of	as such	**Process category (PROC):**

		the substance	(substance itself)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent **Environmental release category (ERC):** ERC 7: Industrial use of substances in closed systems **Subsequent service life relevant for that use?:** no
	4	Formulation and (re)packaging	as such (substance itself)	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent **Environmental release category (ERC):** ERC 2: Formulation of preparations **Subsequent service life relevant for that use?:** no
	5	Industrial use in	as such	**Process category (PROC):**

		coatings	(substance itself)	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 15: Use as laboratory reagent **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles **Subsequent service life relevant for that use?:** no

Table 7. Uses by professional workers

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	6	Professional use in coatings	as such (substance itself) in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities

				PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available. **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Subsequent service life relevant for that use?:** no
	8	Professional use in cleaning agents	as such (substance itself) in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Subsequent service life relevant for that use?:** no
	10	Professional use in metal working fluids/rolling oils	as such (substance itself) in a mixture	**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large

				containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 17: Lubrication at high energy conditions and in partly open process **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Subsequent service life relevant for that use?:** no

Table 8. Uses by consumers

Confidential	IU number	Identified Use (IU) name	Use descriptors
	7	Consumer use in coatings (water based)	**Chemical product category (PC):** PC 9a: Coatings and paints, thinners, paint removes **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Subsequent service life relevant for that use?:** no
	9	Consumer use in cleaning agents	**Chemical product category (PC):** PC 35: Washing and cleaning products (including solvent based products) **Subsequent service life relevant for that use?:** yes
	11	Conusmer use in cosmetics (environment)	**Chemical product category (PC):** PC 39: Cosmetics, personal care products

			Environmental release category (ERC): ERC 8a: Wide dispersive indoor use of processing aids in open systems **Subsequent service life relevant for that use?:** no

Most common technical function of substance (what it does):

Solvents

2.3. Uses advised against

None

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Name: Phenoxypropanol

Implementation: EU

State/form of the substance: liquid

Classification

The substance is classified as follows:

- for physical-chemical properties:

Explosives:	Reason for no classification: conclusive but not sufficient for classification
Flammable gases:	Reason for no classification: conclusive but not sufficient for classification
Flammable aerosols:	Reason for no classification: conclusive but not sufficient for classification
Oxidising gases:	Reason for no classification: conclusive but not sufficient for classification
Gases under pressure:	Reason for no classification: conclusive but not sufficient for classification
Flammable liquids:	Reason for no classification: conclusive but not sufficient for classification
Flammable solids:	Reason for no classification: conclusive but not sufficient for classification
Self-reacting substances and mixtures:	Reason for no classification: conclusive but not sufficient for classification
Pyrophoric liquids:	Reason for no classification: conclusive but not sufficient for classification
Pyrophoric solids:	Reason for no classification: conclusive but not sufficient for classification
Self-heating substances and mixtures:	Reason for no classification: conclusive but not sufficient for classification
Substances and mixtures which in contact with water	Reason for no classification: conclusive but not sufficient for classification

emits flammable gases:	
Oxidising liquids:	Reason for no classification: conclusive but not sufficient for classification
Oxidising solids:	Reason for no classification: conclusive but not sufficient for classification
Organic peroxides:	Reason for no classification: conclusive but not sufficient for classification
Corrosive to metals:	Reason for no classification: conclusive but not sufficient for classification

- for health hazards:

Acute toxicity - oral:	Reason for no classification: conclusive but not sufficient for classification
Acute toxicity - dermal:	Reason for no classification: conclusive but not sufficient for classification
Acute toxicity - inhalation:	Reason for no classification: conclusive but not sufficient for classification
Skin corrosion/irritation:	Reason for no classification: conclusive but not sufficient for classification
Serious damage/eye irritation:	Eye Irrit. 2 (Hazard statement: H319: Causes serious eye irritation.)
Respiration sensitization:	Reason for no classification: data lacking
Skin sensitation:	Reason for no classification: conclusive but not sufficient for classification
Aspiration hazard:	Reason for no classification: conclusive but not sufficient for classification
Reproductive Toxicity:	Reason for no classification: conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:	Reason for no classification: conclusive but not sufficient for classification
Germ cell mutagenicity:	Reason for no classification: data lacking
Carcinogenicity:	Reason for no classification: data lacking
Specific target organ toxicity - single:	Reason for no classification: conclusive but not sufficient for classification
Specific target organ toxicity - repeated:	Reason for no classification: conclusive but not sufficient for classification

- for environmental hazards:

Hazards to the aquatic environment:	Reason for no classification: conclusive but not sufficient for classification
Hazardous to the atmospheric environment:	Reason for no classification: data lacking

Labelling

Signal word: Warning

Hazard pictogram:

GHS07: exclamation mark

Hazard statements:

H319: Causes serious eye irritation.

Precautionary statements:

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

3.2. Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling in Annex I of Directive 67/548/EEC

3.2.2. Self classification(s)

Chemical name: Phenoxypropanol

Table 9. Classification according to Directive 67/548/EEC criteria

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosiveness		conclusive but not sufficient for classification	6.1
Oxidising properties		conclusive but not sufficient for classification	6.3
Flammability		conclusive but not sufficient for	6.2

		classification	
Thermal stability		conclusive but not sufficient for classification	
Acute toxicity		conclusive but not sufficient for classification	5.2
Acute toxicity- irreversible damage after single exposure		conclusive but not sufficient for classification	5.2
Repeated dose toxicity		conclusive but not sufficient for classification	5.6
Irritation / Corrosion	Xi; R36 Irritant; Irritating to eyes.		5.3.4 and 5.4.3
Sensitisation		conclusive but not sufficient for classification	5.5.3
Carcinogenicity		data lacking	5.8.3
Mutagenicity - Genetic Toxicity		conclusive but not sufficient for classification	5.7.3
Toxicity to reproduction-fertility		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction-development		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - breastfed babies		conclusive but not sufficient for classification	5.9.3
Environment		conclusive but not sufficient for classification	7.6

Labelling

Indication of danger:

Xi - irritant

R-phrases:

R36 - irritating to eyes

S-phrases:

S25 - avoid contact with eyes

3.2.3. Other classification(s)

Not applicable

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

In a hydrolysis study with phenoxypropanol no hydro lysis was observed at 50°C and pH 4, 7 and 9. Biodegradation studies in freshwater and in soil are available for phenoxypropanol. Phenoxypropanol was shown to be readily biodegradable according to OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test). In the manometric respirometry test (OECD GL 301F) the time required to achieve 10% degradation of phenoxypropa nol was 5.1 days, while the average extent of biodegradation at the end of the 10 day-window was 72%. The formation of CO2 reached 61% CO2, suggesting the extensive mineralisation of phenoxypropanol. Rapid biodegradation of phenoxypropanol was observed in two different sandy loam soils under aerobic conditions at 25±2 Deg. C Based on the existing biodegradation data in freshwater and soil and considering low potentential for adsorption to sediment. No further biodegradation testing in water and sediment is required. According to REACH Annex IX requirements, sediment simulation testing shall only be considered for substances with a high potential for adsorption to sediment, hence no further simulation tests in water and sediment are required for phenoxypropanol.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

The studies on hydrolysis are summarised in the following table:

Table 10. Overview of studies on hydrolysis

Method	Results	Remarks	Reference
OECD Guideline 111 (Hydrolysis as a Function of pH)	Half-life (DT50): t1/2 (pH 4): at 50 °C (no hydrolysis could be observed) t1/2 (pH 7): at 50 °C (no hydrolysis could be observed) t1/2 (pH 9): at 50 °C (no hydrolysis could be observed) Transformation products: not measured	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (2002a)

Discussion

At 50°C no hydrolysis could be observed.

The following information is taken into account for any hazard / risk / persistency assessment:

A GLP-study according to OECD guideline 111 is available for phenoxypropanol.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

The studies on phototransformation in air are summarised in the following table:

Table 11. Overview of studies on phototransformatio n in air

Method	Results	Remarks	Reference
Method: other: Data estimated using a modeling program. Data estimated using a modeling program EPIWIN AOP (v1.91). Light source: sunlight		3 (not reliable) supporting study Data estimated using a modeling program. **Test material (EC name): 1-phenoxypropan-2-ol**	>>>Author missing<<< (2005a)

Discussion

Data estimated using a modeling program EPIWIN AOP (v1.91). The input to the EPIWIN AOP program was CAS No. 770-35-4.

50 % degradation was observed after 0.3 day(s).

The following information is taken into account for any hazard / risk / persistency assessment:

No experimental data on phototransformation of PPh is available.

Value used for CSA:

Half-life in air: 0.3 d

4.1.1.2.2. Phototransformation in water

This information is not available.

4.1.1.2.3. Phototransformation in soil

This information is not available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Estimated data

This information is not available.

4.1.2.1.2. Screening tests

The test results are summarised in the following table:

Table 12. Overview of screening tests for biodegradation in water

Method	Results	Remarks	Reference
Test type: ready biodegradability activated sludge, domestic (adaptation not specified) OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test)	readily biodegradable % Degradation of test substance: 72 after 28 d (O2 consumption)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1998a)
Test type: inherent biodegradability 1) APHA. Standard method for examination of water and waste water. 14th edition, New York, 1975. 2) Inhouse Dow standard methods	inherently biodegradable, fulfilling specific criteria % Degradation of test substance: 0 after 5 d (TOD) (Using Municipal seed) 3 after 5 d (TOD) (Using Industrial seed) 42 after 20 d (TOD) (Using Municipal seed) 50 after 20 d (TOD) (Using Industrial seed)	3 (not reliable) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1978)

4.1.2.1.3. Simulation tests (water and sediments)

Data waiving

Reason: other justification

Justification: In accordance with column 2 of the REACH Annex IX, simulation testing on ultimate degradation testing in surface water (required in section 9.2.1.2) does not need to be conducted because propylene glycol phenyl ether is readily biodegradable.

4.1.2.1.4. Summary and discussion of biodegradation in water and sediment

Discussion (screening testing)

Propylene glycol phenyl ether was shown to be readily biodegradable according to OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test). In the manometric respirometry test (OECD GL 301F) the time required to achieve 10% degradation of propylene glycol phenyl ether was 5.1 days, while the average extent of biodegradation at the end of the 10 day-window was 72%. The formation of CO_2 reached 61% CO_2, suggesting the extensive mineralisation of propylene glycol phenyl ether.

The following information is taken into account for any hazard / risk / persistency assessment:

Propylene glycol phenyl ether meets the criteria for ready biodegradation passing the 10 day window in OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test). Degradation based on oxygen consumption reached 72 % during 10 day window

Value used for CSA: Biodegradation in water: readily biodegradable

Discussion (simulation testing)

In accordance with column 2 of the REACH Annex IX, simulation testing on ultimate degradation testing in surface water (required in section 9.2.1.2) does not need to be conducted because propylene glycol phenyl ether is readily biodegradable.

The following information is taken into account for any hazard / risk / persistency assessment:

No simulation tests in water and sediment are available for propylene glycol phenyl ether. In accordance with column 2 of the REACH Annex IX, simulation testing on ultimate degradation testing in surface water (required in section 9.2.1.2) does not need to be conducted because propylene glycol phenyl ether is readily biodegradable.

4.1.2.2. Biodegradation in soil

The test results are summarised in the following table:

Table 13. Overview of simulation tests for biodegradation in soil

Method	Results	Remarks	Reference
Test type: laboratory equivalent or similar to OECD Guideline 304 A (Inherent Biodegradability in Soil)	Residues: yes Metabolites: No data	2 (reliable with restrictions) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1991)

Discussion

Studies were carried out on the degradation of A GLP-study equivalent to OECD guideline 304A is available for propylene glycol phenyl ether by soil microorganisms under aerobic condition at 25°C. Three different soil samples, a sandy soil and two sandy loam soils (classified as a Tappan series and a Londo series) were used. Rapid degradation was observed with PPH, where complete degradation occurred within 2 days. The maximum amount of 14C02 produced was 31% of the initially applied radioactivity. 14C-Intermediate compound(s), which were not identified, reached 9.2% of the initially applied radioactivity on day 2 and were not detected on day 7. Since only a 3% loss of parent compound was observed in the killed controls after 7 days, the loss of PPH in the viable microcosms can be attributed to biodegradation.

The following information is taken into account for any hazard / risk / persistency assessment:

A GLP-study equivalent to OECD guideline 304A is available for propylene glycol phenyl ether

Value used for CSA: Half-life in soil: 1 d at 25 °C

4.1.3. Summary and discussion of degradation

Abiotic degradation

No experimental data is available on phototransform ation of phenoxypropanol. Data estimated using a modeling program EPIWIN AOP (v1.91) indicates 50% degradation after 0.3 day(s).

In a GLP-study according to OECD guideline 111 no hydrolysis was observed at 50°C.

Biotic degradation

Biodegradation studies in freshwater and in soil are available for propylene glycol phenyl ether.

Propylene glycol phenyl ether was shown to be readi ly biodegradable according to OECD Guideline 301 F (Ready Biodegradability: Manometric Respirome try Test). In the manometric respirometry test (OECD GL 301F) the time required to achieve 10% degradation of propylene glycol phenyl ether was 5.1 days, while the average extent of biodegradatio n at the end of the 10 day-window was 72%. The formation of CO_2 reached 61% CO_2, suggesting the extensive mineralisation of propylene glycol phenyl ether.
Rapid biodegradation of propylene glycol phenyl ether was observed in two different sandy loam soils under aerobic conditions at 25±2 Deg. C

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 14. Overview of studies on adsorption/desorption

Method	Results	Remarks	Reference
Study type: adsorption (soil) HPLC estimation method OECD Guideline 121 (Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC))	Adsorption coefficient: log Koc: 1.55 at 24 °C	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (2002b)

Discussion

The log Koc for phenoxypropanol at 24°C is 1.55.

The following information is taken into account for any environmental exposure assessment:

A GLP-study according to OECD guideline 121 is available for phenoxypropanol

Value used for CSA:

Koc at 20°C: 1.55

4.2.2. Volatilisation

This information is not available.

4.2.3. Distribution modelling

The data from distribution modelling studies are summarised in the following table:

Table 15. Overview of distribution modelling studies

Method	Results	Remarks	Reference
Media: air, water, soil and sediment Calculation according to Mackay, Level III Calculation programme: The Fugacity model level III program estimates the following half-lives: air = 6.907 hours, water = 360 hours, soil = 360 hours and sediment = 1440 hours. The EPIWIN HENRY program (v3.10) provides a bond estimate of the Henry's Law Constant of 2.05E-008 atm-m3/mole. The EPIWIN PCKOC program (v1.66) calculates a Koc (soil/sediment partition constant) of 18.7. Input data: Not applicable	Percent distribution in media: Air (%): 1.03 Water (%): 46.6 Sediment (%): 52.3 Biota (%): 0.1 Other distribution results: None	3 (not reliable) supporting study Data estimated using a model program. **Test material (EC name): 1-phenoxypropan-2-ol**	>>>Author missing<<< (2005b)
Media: air - biota - sediment(s) - soil - water Calculation according to Mackay, Level III Calculation programme: The Fugacity model level III program estimates the following half-lives: air = 6.907 hours, water = 360 hours, soil = 360 hours and sediment = 1440 hours. The EPIWIN HENRY program (v3.10) provides a bond estimate of the Henry's Law Constant of 2.05E-008 atm-m3/mole. The EPIWIN PCKOC program (v1.66) calculates a Koc (soil/sediment partition constant) of 18.7. Input data: Not applicable	Percent distribution in media: Air (%): 1.03 Water (%): 46.6 Soil (%): 0 Sediment (%): 52.2 Biota (%): 0.1 Other distribution results: None	3 (not reliable) supporting study Data estimated using a model program. **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1997) Staples CA and Davis JW (2002) >>>Author missing<<< (2002)

4.2.4. Summary and discussion of environmental distribution

The log Koc for phenoxypropanol is 1.55 at 24°C.

4.3. Bioaccumulation

No bioaccumulation study is available for phenoxypropanol.

According to REACH Annex VIII column 2, bioaccumulation testing can be waived for substances with a low potential for bioaccumulation (logKow < 3). Propylene glycol phenyl ether has a log Kow < 2. Hence, bioaccumulation testing can be waived for this substance.

4.3.1. Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

Table 16. Overview of studies on aquatic bioaccumulation

Method	Results	Remarks	Reference
The data were estimated using a model program The data were estimated using a model program The data were estimated using a model program Details of method: No data Method: other: estimated using EPIWIN BCF Program (v2.15)	BCF: 0.78	3 (not reliable) supporting study Data estimated using a model program **Test material (EC name): 1-phenoxypropan-2-ol**	>>>Author missing<<< (2005c)

Data waiving

Reason: other justification

Justification: According to REACH Annex VIII column 2, bioaccumulation testing can be waived for substances with a low potential for bioaccumulation (logKow < 3). Propylene glycol phenyl ether has a log Kow < 2. Hence, bioaccumulation testing can be waived for this substance.

4.3.2. Terrestrial bioaccumulation

4.3.3. Summary and discussion of bioaccumulation

Aquatic bioaccumulation

According to REACH Annex VIII column 2, bioaccumulation testing can be waived for substances with a low potential for bioaccumulation (logKow < 3). Propylene glycol phenyl ether has a log Kow < 2. Hence, bioaccumulation testing can be waived for this substance.

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

No bioaccumulation study is available for propylene glycol phenyl ether.

Terrestrial bioaccumulation

This information is not available.

4.4. Secondary poisoning

Interpretation of the available data with regard to the potential to bio-accumulate in the food chain:

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.5.3 "Calculation of PNECoral (secondary poisoning) ".

Justification for no PNEC oral derivation: Propylene glycol phenyl ether is readily biodegradable and has very low potential for bioaccumulation (log Kow <2).

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

The results of experimental studies on absorption, metabolism, distribution and elimination are summarised in the following table:

Table 17. Overview of experimental studies on absorption, metabolism, distribution and elimination

Method	Results	Remarks	Reference
rat (Fischer 344) male oral: gavage Exposure regime: 48 hour(s) Doses/conc.: Males: 10 or 100 mg/kg equivalent or similar to OECD Guideline 417 (Toxicokinetics) equivalent or similar to EPA OPPTS 870.7485 (Metabolism and Pharmacokinetics)	Metabolites identified: yes Details on metabolites: Metabolite profiles of urinary C14-activity were qualitatively and, to some extent, quantitatively similar between dose levels. The following urinary metabolites were tentatively identified within Liquid Chromatography (LC) peaks using HPLC/ESI/MS and HPLC/ESI/MS/MS techniques: LC Peak A (<1%) - Glucuronide conjugate of hydroquinone LC Peak B (1-2%) - Not identified LC Peak C (1.3-3.8%) - Not identified LC Peak D (<1%) - Not identified LC Peak E/F (60-63%) - Sulfate and glutathione conjugates of phenol; Sulfate and glucuronide conjugates of PPh, sulfate conjugates of ring-hydroxylated PPh and 1-phenoxy-2-propanone LC Peak G (<1%) - Not identified LC Peak H (1-2%) - Not identified LC Peak I (4-5%) - Glucuronide conjugate of PPh LC Peak J (<1%) - Not identified LC Peak K (8-9%) - Glucuronide conjugate of PPh LC Peak L (9- 10%) - Sulfate conjugate of PPh Based on comparisons of chromatographic retention times with authentic materials, acid hydrolysis of urine yielded free phenol (61%), hydroquinone (1.5%), and parent PPh (13%). Evaluation of results: no bioaccumulation potential based on study results	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (2002) Saghir SA, Brzak KA and Bartels MJ (2003)

5.1.2. Human information

No human data available.

5.1.3. Summary and discussion of toxicokinetics

Based on the results of a study in male rats, PPh is rapidly absorbed, distributed, and quickly metabolized and eliminated. Virtually all the administered dose is eliminated within 48 hours in the urine and feces. The three major routes of metabolism are 1) cleavage of PPh by O-dealkylation, yielding propylene glycol and phenol, followed by excretion of phenol as a sulfate, or glutathione conjugate in the urine; 2) direct sulfate or glucuronide conjugation of parent PPh and excretion into the urine; and 3) ring hydroxylation of parent PPh or its oxidized propanone metabolite, followed by sulfate conjugation and excretion into the urine. Minor urinary metabolites included the glucuronide conjugate of hydroquinone. PPh is rapidly absorbed, distributed throughout the body, and eliminated, similar to other propylene glycol ethers (PGEs). The major routes of elimination, urine and feces, also are similar to other PGEs. The types of metabolites, parent ether conjugates, hydrolyzed propylene glycol, and hydrolyzed alcohol (phenol) conjugates, also are similar.

Basic toxicokinetics

Adult, male F344 rats were administered a single oral dose of 10 or 100 mg/kg radiolabeled DOWANOL PPh. The major route of elimination of DOWANOL PPh was through urine, accounting for 88 ± 12% of the low and 96 ± 3% of the high dose. Most of the urinary excretion of DOWANOL PPh derived radioactivity occurred within 12 hr after dosing; 81 ± 9% of the low and 90 ± 1% of the high dose. Total fecal elimination remained < 10% during the course of the study. Rats eliminated the entire administered dose within 48 hr after dosing, with total recovery ranging from 100 – 106%. Metabolites tentatively identified in urine were conjugates of phenol (sulfate, glutathione), as well as conjugates of parent compound (glucuronide, sulfate) and a ring-hydroxylated metabolite of parent. There was no free parent compound or phenol detected in non-acid-hydrolyzed urine. In acidhydrolyzed urine, 61% of the dose was identified as phenol and 13% as DOWANOL PPh. Although the parent compound was stable to acid hydrolysis, some of the phenol in acid hydrolyzed urine may have come from degradation of acid-labile metabolite(s) as well as hydrolysis of phenol conjugates.

The following information is taken into account for any hazard / risk assessment:

A GLP-study on metabolism of PPh in rats after oral administration is available for phenoxypropanol

Value used for CSA: no bioaccumulation potential

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of experimental studies are summarised in the following table:

Table 18. Overview of experimental studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD50: > 2000 mg/kg bw (male/female)	2 (reliable with restrictions) key study experimental result **Test material (EC**	BASF AG (1987) OECD (2006a)

		name): 1-phenoxypropan-2-ol	
rat male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD50: 2830 mg/kg bw (male) LD50: 3730 mg/kg bw (female)	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1968)

5.2.1.2. Acute toxicity: inhalation

The results of experimental studies are summarised in the following table:

Table 19. Overview of experimental studies on acute toxicity after inhalation exposure

Method	Results	Remarks	Reference
rat (Wistar) male/female inhalation: aerosol (nose/head only) OECD Guideline 403 (Acute Inhalation Toxicity)	LC50 (4 h): > 5.4 mg/L air (male/female) ((5400 mg/m3))	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1991a)

5.2.1.3. Acute toxicity: dermal

The results of experimental studies are summarised in the following table:

Table 20. Overview of experimental studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
rat (HanIbm : WIST (SPF)) male/female Coverage: semiocclusive OECD Guideline 402 (Acute Dermal Toxicity)	LD50: > 2000 mg/kg bw (male/female) (no deaths occurred at this dose level)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1986)
rabbit equivalent or similar to OECD Guideline 402 (Acute Dermal	LD50: > 2000 mg/kg bw	2 (reliable with restrictions) supporting study	The Dow Chemical Company (1968)

Toxicity)		experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	

5.2.1.4. Acute toxicity: other routes

This information is not available.

5.2.2. Human information

No human data available.

5.2.3. Summary and discussion of acute toxicity

Oral: two non-GLP studies equivalent to OECD guideline 401 have been conducted with phenoxypropanol in rats. Both studies report LD50 greater than 2000 mg/kg bw/day.

Dermal: in a GLP-study according to OECD guideline 402 the dermal LD50 of phenoxypropanol in rats was greater than 2000 mg/kg bw. This data is s upported by a non-GLP study similar to OECD guideline 402 which reports a dermal LD50 greater than 2000 mg/kg bw in rabbits.

Inhalation: in a GLP-study according to OECD guideline 403 the LC50 of phenoxypropanol (liquid aerosol) was greater than 5.4 mg/L (highest concent ration tested). No mortality was observed in this study.

The following information is taken into account for any hazard / risk assessment:

Non-GLP studies equivalent or similar to OECD guidelines 401 and 402 as well as GLP-studies according to OECD guidelines 402 and 403 are available for phenoxypropanol.

Value used for CSA:

LD50 (oral): 2830 mg/kg bw

LD50 (dermal): 2000 mg/kg bw

LC50 (inhalation): 5400 mg/m³ air

Justification for classification or non classification

LD50 values for oral and dermal route are greater than 2000 mg/kg/bw and no mortality has been observed after inhalation exposure to phenoxypropan ol up to the highest dose tested. According to the EU criteria for classification and labeling, phenox ypropanol is not classified for acute toxicity for any route of exposure.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

The results of experimental studies on skin irritation are summarised in the following table:

Table 21. Overview of experimental studies on skin irritation

Method	Results	Remarks	Reference
rabbit (Vienna White) Coverage: semiocclusive (clipping of the fur was done at least 15 hours before the beginning of the study) OECD Guideline 404 (Acute Dermal Irritation / Corrosion)	not irritating Erythema score: 0 of max. 4 (mean) (Time point: 24-48-72-hour) (not applicable) (only one animal showed a positive response (score 1) directly after treatment, which was reversible within 24 hours) Edema score: 0 of max. 4 (mean) (Time point: 24-48-72-hour) (not applicable)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1991b) OECD (2006b)

5.3.1.2. Human information

No human data available.

5.3.2. Eye

5.3.2.1. Non-human information

The results of experimental studies on eye irritation are summarised in the following table:

Table 22. Overview of experimental studies on eye irritation

Method	Results	Remarks	Reference
rabbit (New Zealand White) EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	irritating Cornea score: 1 (animal #1) (Time point: 24, 48 and 72 hours) (fully reversible within: 14 days) 1 (animal #2) (Time point: 24, 48 and 72 hours) (fully reversible within: 14 days) 1 (animal #3) (Time point: 24, 48 and 72 hours) (fully reversible within: 14 days) Iris score: 0.7 (animal #1) (Time point: 24, 48 and 72 hours) (fully reversible within:	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1998b)

	7 days) 0.3 (animal #2) (Time point: 24, 48 and 72 hours) (fully reversible within: 72 hours) 0.7 (animal #3) (Time point: 24, 48 and 72 hours) (fully reversible within: 72 hours) Conjunctivae score: 2.3 (animal #1) (Time point: 24, 48 and 72 hours) (fully reversible within: 14 days) 3 (animal #2) (Time point: 24, 48 and 72 hours) (fully reversible within: 14 days) 2.7 (animal #3) (Time point: 24, 48 and 72 hours) (fully reversible within: 14 days) Chemosis score: 1.3 (animal #1) (Time point: 24, 48 and 72 hours) (fully reversible within: 7 days) 1.3 (animal #2) (Time point: 24, 48 and 72 hours) (fully reversible within: 7 days) 1 (animal #3) (Time point: 24, 48 and 72 hours) (fully reversible within: 72 hours)		
rabbit (Vienna White) OECD Guideline 405 (Acute Eye Irritation / Corrosion)	irritating Cornea score: 1 of max. 4 (mean) (Time point: 24-48-72-hour) (not fully reversible within: 23 days; 2 animals still showing positive readings (1) at the end of the observation period) Iris score: 0.4 of max. 3 (mean) (Time point: 24-48-72-hour) (fully reversible within: 48 hours) Conjunctivae score: 2 of max. 4 (mean) (Time point: 24-48-72-hour) (not fully reversible within: 23 days; the 3 animals still showing positive readings (1, 2 and 3 respectively) at the end of the observation period) Chemosis score: 0.9 of max. 4 (mean) (Time point: 24-48-72-hour) (not fully reversible within: 8 days; 1 animals still showing positive readings (1) at post treatment	1 (reliable without restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1991c) OECD (2006b)

	day 8)		
rabbit not applicable	slightly irritating : (scores not available)	4 (not assignable) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1968)

5.3.2.2. Human information

No human data available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

This information is not available.

5.3.3.2. Human information

No human data available.

5.3.4. Summary and discussion of irritation

Skin: no irritation was observed in any of the test animals after dermal application of phenoxypropanol. The mean scores for both erythema and edema were 0 at 24, 48 and 72 hours.

Eye: in both studies conducted with phenoxypropanol reversible irritation was observed after application to rabbit eyes.

The following information is taken into account for any hazard / risk assessment:

A GLP study according to OECD guideline 404 and two GLP-studies according to OECD guideline 405 are available for phenoxypropanol.

Value used for CSA:

Skin irritation / corrosion: not irritating

Eye irritation: irritating

Justification for classification or non classification

Skin irritation: according to EEC Council Directive 67/548/EEC (amended by Directive 83/467/EEC) and GHS/CLP the mean value for erythema and edema scores was 0 for all animals at any time. Hence, phenoxypropanol is not classified as skin irritant.

Eye irritation: according to the annex VI of the council directive 67/548 EEC (amended by directive 83/467 EEC) and GHS/CLP the maximum average scores of the 3 animals for cornea opacity, iris lesions, conjunctivae and chemosis were 1.0, 0.7, 3.0 and 1.3, respectively at 24, 48 and 72 hours. All effects were reversible within 14 days. According to EU criteria phenoxypropanol is classified for eye irritation.

5.4. Corrosivity

5.4.1. Non-human information

See paragraph on irritation.

5.4.2. Human information

No human data available.

5.4.3. Summary and discussion of corrosion

Not applicable.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of experimental studies on skin sensitisation are summarised in the following table:

Table 23. Overview of experimental studies on skin sensitisation

Method	Results	Remarks	Reference
guinea pig (Hartley) male Buehler test Induction: epicutaneous, occlusive Challenge: epicutaneous, occlusive OECD Guideline 406 (Skin Sensitisation) EPA OTS 798.4100 (Skin Sensitisation) MAFF Dermal Sensitization Study, 1985.	not sensitising Stimulation index: not applicable No. with positive reactions: 1st reading: 0 out of 20 (test group); 24 h after chall.; dose: 0.4 ml of 100% DOWANOL PPh 2nd reading: 0 out of 20 (test group); 48 h after chall.; dose: 0.4 ml of 100% DOWANOL PPh	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1998c)
guinea pig (Dunkin-Hartley) female Guinea pig maximisation test Induction: intradermal and epicutaneous Challenge: epicutaneous, occlusive OECD Guideline 406 (Skin Sensitisation)	not sensitising No. with positive reactions: 1st reading: 0 out of 5 (negative control); 24 h after chall.; dose: 100% 2nd reading: 0 out of 5 (negative control); 48 h after chall.; dose: 100% 1st reading: 0 out of 10 (test group); 24 h after chall.; dose: 100% 2nd reading: 0 out of 10 (test group); 48 h after chall.; dose: 100% 1st reading: 10 out of 10 (positive control); 24 h after chall.; dose: 25%	1 (reliable without restriction) key study experimental result **Test material (Common name): phenoxypropanol**	BASF AG (1998a)

	2nd reading: 9 out of 10 (positive control); 48 h after chall.; dose: 25%		

5.5.1.2. Human information

No human data available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

This information is not available.

5.5.2.2. Human information

No human data available.

5.5.3. Summary and discussion of sensitisation

Skin sensitisation

In both available studies (Buehler and GMPT) no induction of contact hypersensitivity was observed, none of the 20 animals tested in each study showed a positive reaction. Hence, phenoxypropanol is not considered to be a skin sensitzer.

The following information is taken into account for any hazard / risk assessment:

Two GLP-studies according to OECD guideline 406 (Buehler and Maximization test) are available for phenoxyproppanol.

Value used for CSA: not sensitising

Respiratory sensitisation

Based on the clearly negative results of the two skin sensitization studies phenoxypropanol is not expected to be a respiratory sensitizer.

The following information is taken into account for any hazard / risk assessment:

No data on respiratory sensitization is available for phenoxypropanol.

Value used for CSA: not sensitising

Justification for classification or non classification

No sensitization reaction was observed with phenoxy propanol. In both the Maximization test (0/20) and the Buehler test (0/20) the sensitization rate was 0%. According to EU criteria for classification and labelling requirements for dangerous substances as laid down in Annex VI of the EEC Council Directive 671548lEEC (amended by Directive 83/467/EEC) and according to GHS/CLP, phenoxypropanol is not classified as a sensitiser.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of experimental studies are summarised in the following table:

Table 24. Overview of experimental studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) male/female subchronic (oral: drinking water) 0, 500, 2000, and 6000 ppm (nominal in water) 0, 35/46, 146/177, and 429/486 mg/kg bw in males/females (calculated based on water consumption) (actual ingested) Exposure: 90 days (continuously in drinking water) OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)	NOAEL: 146 mg/kg bw/day (nominal) (male) (Based on impairment of body weight (5.7% below control on day 91 being) and body weight change (9.2% below control on day 91) in males, and discoloration of urine in both sexes) NOEL: ca. 35 — ca. 46 mg/kg bw/day (nominal) (male/female)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1997a)
rat (Wistar) male/female subchronic (oral: drinking water) 100 ppm (11.3 mg/kg body weight/day (mean dose)) 1000 (113.9 mg/kg body weight/day (mean dose)) 5000 (477.5 mg/kg body weight/day (mean dose)) Exposure: 26 weeks (7 days/week (daily exposure via drinking water)) OECD Guideline 416 (Two-Generation Reproduction Toxicity Study)	NOAEL: 1000 ppm (male/female) based on: drinking water (Signs of general, systemic toxicity were noted in both parental generations (F0 and F1) in groups receiving 5000 ppm, but not in others. Toxicity was characterized by decreased water and food consumption, decreased body weight and body weight gain in parental F0 an F1 males and females. Pathology and histopathology did not reveal substance-related adverse effects in F0 and F1 parental animals.) NOAEL: 477.5 mg/kg bw/day (actual dose received) (male/female) based on: test mat. (Signs of general, systemic toxicity were noted in both parental generations (F0 and F1) in groups receiving 5000 ppm, but not in others. Toxicity was characterized by decreased water and food consumption, decreased body weight and	1 (reliable without restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF (2000)

	body weight gain in parental F0 an F1 males and females. Pathology and histopathology did not reveal substance-related adverse effects in F0 and F1 parental animals.)		
rat (Wistar) male/female subacute (oral: drinking water) 82/106, 248/279 and 795/801 mg/kg per day (in males / females, calculated based on water consumption (actual ingested) 1000, 3000 and 10000/6000 ppm (nominal in water) Exposure: 28 days (continuously in drinking water) OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)	NOEL: 82 — 106 mg/kg bw/day (nominal) (male/female) LOAEL: 248 — 279 mg/kg bw/day (nominal) (male/female) (Increased mean absolute (males) and relative (both sexes) kidney weights, decreased mean absolute weight of the epididymides and brownish discoloration of urine in females.)	1 (reliable without restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1999a)

5.6.1.2. Repeated dose toxicity: inhalation

This information is not available.

5.6.1.3. Repeated dose toxicity: dermal

The results of experimental studies are summarised in the following table:

Table 25. Overview of experimental studies on repeated dose toxicity after dermal administration

Method	Results	Remarks	Reference
rabbit (New Zealand White) male/female subchronic 100 mg/kg body weight/day (nominal per unit body weight) 300 mg/kg body weight/day (nominal per unit body weight) 1000 mg/kg body weight/day (nominal per unit body weight) Exposure: 28 days (once daily, 5 days/week (19 applications total)) equivalent or similar to OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study)	NOAEL (for systemic toxicity): 1000 mg/kg bw/day (nominal) (male/female) (based on overall effects) NOAEL (for local effects on the skin): 100 mg/kg bw/day (nominal) (male/female) (based on - histopathologic examination revealed a thickening of the epidermis at the application site which was considered to be an adaptive response to treatment rather than an adverse effect)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1986a)

equivalent or similar to EPA OPPTS 870.3200 (Repeated Dose Dermal Toxicity -21/28 Days)			
rabbit (New Zealand White) female subacute 1000 mg/kg bw/day (nominal per unit body weight) Exposure: 14 days (24 hr/day, 7 days/week) equivalent or similar to EPA OPPTS 870.3200 (Repeated Dose Dermal Toxicity -21/28 Days)	NOAEL: 1000 mg/kg bw/day (female) based on: test mat. (based on overall effects)	1 (reliable without restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1985)

5.6.1.4. Repeated dose toxicity: other routes

This information is not available.

5.6.2. Human information

No human data available.

5.6.3. Summary and discussion of repeated dose toxicity

Discussion

Oral: In a 90-day drinking water study in rats concentrations of 500, 2000 and 6000 ppm have been used. At 500 ppm no substance related effects have been observed and at 2000 ppm the only effects observed were decreased body weight (less than 10%) and discoloration of urine. Therefore, the 2000 ppm (146 mg/kg bw/d) dose level is considered to be the NOAEL and will be used as critical dose descriptor to derive the DNEL.

This data is supported by the results of a 2-generation reproductive toxicity study in rats and the 4 week range finder for this study, both conducted via drinking water administration of the test material. PPh was administered to two generations of rats (25/sex/group) in for 26 weeks at concentrations of 100, 1000, or 5000 ppm (equivalent to doses of 0, 11.3, 113, or 478 mg/kg-d) (this study is also discussed in section 7.8.1). Effects were seen only at the highest exposure concentration that manifested as reduced body weights and corresponding reduced food and water consumption. No clinical signs were evident during the course of exposure and no gross or histopathological lesions were seen at autopsy. The NOEL for this drinking water study with rats was 1000 ppm (113 mg/kg-d) and the LOAEL was 5000 ppm (478 mg/kg-day), based on body weight changes.

Dermal: two GLP-studies in rabbits are available for the dermal route of exposure. In a 28-day study no systemic effects have been observed up to the limit dose of 1000 mg/kg bw/day. Mild dermal irritation characterized by slight hyperemia and moderate exfoliation was observed in the 1000 mg/kg/day animals. Slight exfoliation was observed in most of the 300 mg/kg/day animals (slight hyperemia was also present for females), while 100 mg/kg/day animals showed only very slight exfoliation. Therefore, the NOAEL for local effects is 100 mg/kg bw/day. This is supported by a 14-day study where no systemic effects have been observed at the limit dose of 1000 mg/kg bw/day, but dermal irritation was evident at this dose level.

Inhalation: no studies via the inhalation route are available for PPh. However, based on the low vapor pressure of this material inhalation exposure is not considered to be relevant.

The following information is taken into account for any hazard / risk assessment:

Two repeated dose dermal toxicity studies (14-days and 28-days) in rabbits are available for phenoxypropanol. Both studies have been conduced under GLP and are equivalent or similar to OECD guideline 410. For the oral route 3 GLP-studies according to OECD guidelines 407, 408 and 416 have been conducted in rats using drinking water administration of the test material.

Value used for CSA (route: oral):

NOAEL: 146 mg/kg bw/day (subchronic; rat)

Target organs: urogenital: kidneys

Value used for CSA (route: dermal):

NOAEL: 1000 mg/kg bw/day (subacute; rabbit)

Justification for classification or non classification

The no observed adverse effect levels for phenoxypropanol exceed the values triggering classification. Therefore no classification for prolonged exposure is required.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of experimental studies are summarised in the following table:

Table 26. Overview of experimental in vitro genotoxicity studies

Method	Results	Remarks	Reference
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) Salmonella typhimurium strains TA98, TA100, TA1535, and TA1537 (met. act.: with and without) Doses: standard plate test : 0, 20, 100, 500, 2500 & 5000 µg/plate +/- S9 mix from Arochlor-induced rat liver preincubation test : 0, 20, 100, 500, 2500 & 5000 µg/plate +/- S9 up to 5000 micrograms per plate OECD Guideline 471 (Bacterial Reverse Mutation Assay) OECD Guideline 472 (Genetic Toxicology: Escherichia coli, Reverse Mutation Assay) EU Method B.13/14 (Mutagenicity - Reverse Mutation Test Using Bacteria)	Evaluation of results: negative Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100(all strains/cell types tested); met. act.: with and without; cytotoxicity: no, but tested up to limit concentrations	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1998b)
mammalian cell gene mutation assay (gene mutation) L5178Y Mouse Lymphoma Cells (met. act.: with and without) Doses: 300 - 1510 µg/ml OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)	Evaluation of results: negative Test results: negative for mouse lymphoma L5178Y cells(all strains/cell types tested (L5178Y Mouse Lymphoma Cells)); met. act.: with and without; cytotoxicity: yes (1510 µg/ml)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (2002c)
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (met. act.: with and without) Doses: up to 5000 micrograms per plate no data available	Evaluation of results: negative Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100(all strains/cell types tested); met. act.: with and without; cytotoxicity: not reported	4 (not assignable) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	Bootman J and May K (December, 1985) (1985) ECETOC Monograph (1995a)

in vitro mammalian chromosome aberration test (chromosome aberration) Cultured Chinese hamster ovary (CHO) cells (met. act.: with and without) Doses: 34 - 1510 µg/ml OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	Evaluation of results: negative Test results: negative for Chinese hamster Ovary (CHO)(strain/cell type: Cultured Chinese hamster ovary (CHO) cells); met. act.: with and without; cytotoxicity: yes (equal or higher than 50% (see below); only occurring only after 20 hours treatment and without S-9 Mix at concentration levels equal or higher than 966.4 µg/ml)	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (2002d)
in vitro mammalian chromosome aberration test (chromosome aberration) lymphocytes: peripheral human (met. act.: with and without) Doses: up to 400 micrograms per milliliter culture medium no data	Evaluation of results: negative Test results: negative for lymphocytes: peripheral human; met. act.: with and without; cytotoxicity: not reported	4 (not assignable) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	Bootman J (1986) ECETOC Monograph (1995b)

5.7.1.2. In vivo data

The results of experimental studies are summarised in the following table:

Table 27. Overview of experimental in vivo genotoxicity studies

Method	Results	Remarks	Reference
micronucleus assay (chromosome aberration) mouse (CD-1) male/female oral: gavage 500 mg/kg body weight (nominal conc. (target concentration - 50 mg/l; observed concentration - 45.1 mg/l)) 1000 mg/kg body weight (nominal conc. (target concentration - 100 mg/l; observed concentration - 93.4 mg/l)) 2000 mg/kg body weight (nominal conc. (target concentration - 200 mg/l; observed concentration - 182 mg/l))	Evaluation of results: negative Test results: Genotoxicity: ambiguous (male/female); toxicity: yes	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (2000)

OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) EPA OPPTS 870.5395 (In Vivo Mammalian Cytogenics Tests: Erythrocyte Micronucleus Assay)			

5.7.2. Human information

No human data available.

5.7.3. Summary and discussion of mutagenicity

Discussion

In the AMES test, no increase in mutant frequency was observed in either standard plate or preincubation test in the absence or presence of metabolic activation. Hence, under the conditions of the study, phenoxypropanol was not considered to be mutagenic in bacteria.

In an in vitro mouse lymphoma assay test no statistically significant increases in mutant frequency were observed following treatment with the test substance at any dose level tested in the absence or presence of S-9 in Experiment 1 or 2. It is concluded that, under the conditions employed in this study, the test substance is not mutagenic to mammalian cells in this test system when tested up to a maximum concentration of 10 mM in the absence and presence of S-9.

In an in vitro chromosome aberration assay in CHO cells, frequencies of cells with structural aberrations observed in the absence and presence of S-9 (all experiments) were similar to those observed in concurrent vehicle controls. The aberrant cell frequency of all test substance treated cultures fell within historical negative control (normal) ranges. Hence, phenxoypropanol is not considered to be a clastogenic agent in mammalian cells.

In an in vivo micronucleus test, groups of 6 male mice were administered 0, 500, 1000, or 2000 mg PPh/kg body weight by gavage on 2 consecutive days by oral intubation. Because hypothermia resulted from treatment in this Phase 1 study, particularly in the high dose subjects, the experiment was repeated with both sexes (Phase 2) with 6 additional animals in the high dose group to serve as replacements in the event of mortality. In Phase 1, 1 of 6 males died from treatment in the high dose group (2000 mg/kg/day). Autopsy did not reveal a cause for death. Three males from this group (including the one that died) showed clinical signs of shallow breathing, decreased to absent activity, and hypothermia. The two surviving animals showing hypothermia were placed in a warm environment. No deaths, clinical signs, or hypothermia occurred in the lower dose groups or in the cyclophosphamide control groups. The high dose group showed an average increased frequency of micronuclei. The %MN-PCE (% micronuclei) values from two animals with hypothermia accounted for the increased average of this group and the authors of the study attributed the increase to hypothermia. These values were 18.0 % and 11.5% while the values in the three other survivors were 1.0%, 4.5%, and 3.0%, similar to the corn oil control group values. In Phase 2, the effects seen in Phase 1 were observed again in the 2000 mg/kg/day group. Although not statistically significant, the %MN-PCE was elevated once more. Marked hypothermia was observed yet again at this dose level only in both sexes. As in Phase 1, the ratio of polychromatic (PCE) to normo-chromatic erythrocytes (NCE) was decreased in the high dose group. Only males (6/dose level) were used in phase 1 while male and females (6/sex/dose level) were used in phase two. The authors of this study concluded that, most likely, the increased incidence of micronuclei seen at 2000 mg/kg/day was attributable to the hypothermia induced by PPh and not as a direct clastogenic effect from PPh. The authors cited papers by Asanami et al. (Asanami, S., Shimono, K., (1997). High body temperature induces micronuclei in mouse bone marrow. Mutation Research, 390:70-83 and Asanami, S., Shimono, K., Kaneda, S., (1998). Transient hypothermia induces micronuclei in mice. Mutation Research, 413:7-14) showing that agents such as reserpine and

chlorpromazine, which induce hypothermia, cause increased micronuclei as an indirect result of this physiological change. Asanami et al. hypothesize that hypothermia may cause clastogenic injury by interfering with microtubule assembly and spindle function. Since a separate, additional group at the high dose level was not placed in a warmed environment after treatment to directly test the hypothesis of hypothermia causing the increased micronuclei, the possibility that the increased incidence of micronuclei at the high dose was directly attributable to PPh cannot be excluded. On the other hand, it is relevant to note that the next lower dose (still a very large dose of 1000 mg/kg) did not cause hypothermia or an increase in micronuclei. If the increase was directly attributable to PPh and not hypothermia, it is significant that only a marginal effect resulted (not statistically significant when repeated in a second experiment), which required a very large dose of 2000 mg/kg.

The following information is taken into account for any hazard / risk assessment:

GLP studies according to OECD guidelines 471, 473, 476 and 474 are available for phenoxypropanol.

Value used for CSA: Genetic toxicity: negative

Justification for classification or non classification

Phenoxypropanol was not mutagenic in bacteria (Salmonella typhimurium TA 1535, TA 1537, TA 1538, TA 98, and TA 100) and in mammalian cells in vitro. Phenoxypropanol was also not considered to be clastogenic in vitro and in vivo. Hence, the data available indicates that phenoxypropanol is not genotoxic and no classification is required according to EU criteria.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

This information is not available.

5.8.1.2. Carcinogenicity: inhalation

This information is not available.

5.8.1.3. Carcinogenicity: dermal

This information is not available.

5.8.1.4. Carcinogenicity: other routes

This information is not available.

5.8.2. Human information

No human data available.

5.8.3. Summary and discussion of carcinogenicity

Not applicable.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of experimental studies are summarised in the following table:

Table 28. Overview of experimental studies on fertility

Method	Results	Remarks	Reference
rat (Wistar) male/female two-generation study oral: drinking water (not applicable) 0 ppm (nominal in water) 100 ppm (nominal in water) (11.3 mg/kg body weight/day (mean dose)) 1000 ppm (nominal in water) (113.9 mg/kg body weight/day (mean dose)) 5000 ppm (nominal in water) (477.5 mg/kg body weight/day (mean dose)) Exposure: Exposure period: 26 weeks Premating exposure period (males): 77 days Premating exposure period (females): 77 days Duration of test: 40 weeks (7 days/week) OECD Guideline 416 (Two-Generation Reproduction Toxicity Study)	NOAEL (P): 5000 ppm (male/female) based on: test mat. (based on reproductive performance and fertility) NOAEL (P): 1000 ppm (male/female) based on: test mat. (Signs of general, systemic toxicity were noted in both parental generations (F0 and F1) in groups receiving 5000 ppm, but not in others. Toxicity was characterized by decreased water and food consumption, decreased body weight and body weight gain in parental F0 an F1 males and females. Pathology and histopathology did not reveal substance-related adverse effects in F0 and F1 parental animals.) NOAEL (F1): 1000 ppm (male/female) based on: test mat. (based on the following effects noted in the animals administered 5000 ppm - reduction in the weaning body weight on day21 and a retardation in sexual maturation as evidenced by delayed preputial separation and vaginal opening in the selected F1 male and female animals.) NOAEL (F2): 1000 ppm (male/female) based on: test mat. (based on the following effects noted in animals adminsitered 5000 ppm - reduced body weight and body weight changes and organ weight changes (both sexes combined) - significantly lower mean absolute weights of brain (-	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF (2000)

	6%), thymus (-23%) and spleen (-34%) compared to controls. Significant relative organ weight changes were noted for brain (+30%) and spleen (-18%).)		

Toxicity to reproduction: other studies

The results of experimental studies are summarised in the following table:

Table 29. Overview of experimental studies on the toxicity to reproduction (other studies)

Method	Results	Remarks	Reference
rabbit (New Zealand White) male/female dermal (not applicable) 100 mg/kg body weight/day (nominal conc.) 300 mg/kg body weight/day (nominal conc.) 1000 mg/kg body weight/day (nominal conc.) Exposure: 28 days (Once daily, 5 days/week (19 applications total)) Guideline 870.3200 "21/28-Day dermal toxicity" and OECD 410: "Repeated Dose Dermal Toxicity: 21/28 day."	NOAEL: 1000 mg/kg bw/day (male/female) (No toxicity to reproductive organs was evident based on organ weights, gross observation, or microscopic examination)	1 (reliable without restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1986b)

5.9.1.2. Human information

No human data available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

The results of experimental studies are summarised in the following table:

Table 30. Overview of experimental studies on developmental toxicity

Method	Results	Remarks	Reference
rat (Wistar) oral: gavage 40, 160, 640 mg/kg per day (actual ingested) Exposure: day 6-19 post coitum (pc) (daily, 7 days/week) OECD Guideline 414 (Prenatal Developmental Toxicity Study)	NOAEL (embryotoxicity): 160 mg/kg bw/day NOAEL (maternal toxicity): 40 mg/kg bw/day NOAEL (teratogenicity): > 640 mg/kg bw/day	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (2000)
rabbit (Himalayan) oral: gavage 60, 180, 540 mg/kg per day (actual ingested) Exposure: d 7-19 post insemination (daily, 7 d/wk) OECD Guideline 414 (Prenatal Developmental Toxicity Study)	NOAEL (embryotoxicity): 180 mg/kg bw/day NOAEL (teratogenicity): > 540 mg/kg bw/day NOAEL (maternal toxicity): 180 mg/kg bw/day LOAEL (maternal toxicity): 540 mg/kg bw/day (actual dose received) (reduced food intake, reduced body weight gain, adverse clinical symptoms (e.g. apathy/lateral position))	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1995) OECD (2006c)

5.9.2.2. Human information

No human data available.

5.9.3. Summary and discussion of reproductive toxicity

Discussion

Effects on fertility

In a 2-generation reproductive toxicity study in rats, phenoxypropanol was continuously administered with drinking water over two parental generations at concentrations of 0, 100, 1000 and 5000 ppm. Reproductive performance or fertility was not affected in F0 or F1 parental animals of either dose group. Estrous cycle, mating behavior, conception, gestation, parturition, lactation and weaning as well as sperm parameters, sexual organ weights, and gross and histopathological findings of these organs were similar between control and treated animals. Signs of general, systemic toxicity were noted in both parental generations (F0 and F1) in groups receiving 5000 ppm, but not in others. Toxicity was characterized by decreased water and food consumption, decreased body weight and body weight gain in parental F0 an F1 males and females. Pathology and histopathology did not reveal substance-related adverse effects in F0 and F1 parental animals. The clinical, gross and histopathological examinations in F0 and F1 parental animals from the low and intermediate dose groups did not yield any indication of systemic toxicity. Substance-related signs of develomental toxicity were seen in progeny of the high dose (5000 ppm) F0 and F1 parents in terms of reduced pup body weight and body weight gain. This is directly related to lower absolute weights of the thymus, spleen and brain in pups and delayed sexual maturation. Moreover, reproduction parameters of these animals were not adversely affected after gaining sexual maturity. This supports the view that delayed preputial separation and vaginal opening resulted from a general retardation of physical development. No signs of developmental toxicity were seen in pups from groups receiving medium or low doses (1000 or 100 ppm, respectively.). Under the conditions of this study, NOAELs were established as follows:

NOAEL for reproductive performance and fertility: 5000 ppm (about 477.5 mg PPh/kg body weight/day) for the F0 and F1 parents NOAEL for developmental toxicity: 1000 ppm (about 113.9 mg PPh/kg body weight/day) for the F1 and F2 progeny

NOAEL for general systemic toxicity: 1000 ppm (about 113.9 mg PPh/kg body weight/day) for the F0 and F1 parents

Thus, developmental toxicity was seen only at a dose which was also toxic to the parent animals. No sign of teratogenicity was seen at either dose in this study.

The following information is taken into account for any hazard / risk assessment:

A GLP-study according to OECD guideline 416 - conducted in rats - is available for phenoxypropanol. The test material was administered via the drinking water.

Value used for CSA (route: oral): NOAEL: 477.5 mg/kg bw/day

Developmental toxicity

In a teratology study in rabbits using oral gavage administration of phenoxypropanol, the administration of test substance to pregnant Himalayan rabbits during organogenesis induced overt maternal toxicity at 540 mg/kg body weight/day, but was not toxic to the does at 60 and 180 mg/kg body weight/day. Maternal toxicity at the highest dose level was substantiated by reduced food consumption, impairments in body weight gain and adverse clinical symptoms (e. g. apathy/lateral position). Signs of developmental toxicity occurred only at the highest dose level (540 mg/kg body weight/day) in the form of an increased occurrence of skeletal variations (predominantly accessory 13th rib(s)); however, no substance-induced teratogenic effects were observed up to and including the dose of 540 mg/kg body weight/day. At 60 and 180 mg/kg body weight/day no influence on the gestational parameters and no signs of developmental toxicity, especially no substance-induced indications of teratogenicity, were observed. For this prenatal toxicity study in Himalayan rabbits, the no observed adverse effect level (NOAEL) concerning maternal and developmental toxicity is 180 mg/kg body weight/day.

In a second teratology study in rats also using oral gavage administration of phenxoypropanol, dose-related overt signs of maternal toxicity were seen in animals receiving 640 or 160 mg/kg per day.

Transient salivation, apathy and piloerection occurred in several high dose animals after gavage. Compared with control animals, significant changes in food consumption (-14%), body weight gain (-20%), corrected body weight gain (-43%) and carcass weight (-6%) was noted in the high dose animals. Gestational parameters were not affected. Less severe signs of toxicity were seen in the animals receiving 160 mg/kg per day. The effects on food intake (-6%) and body weight (BWC -16%; corrected BWC -18%) were less pronounced. Again, gestational parameters were not affected. No substance-related effects on dams were seen in animals receiving 40 mg/kg per day. Prenatal developmental toxicity was seen in fetuses from dams receiving 640 mg/kg per day in terms of significantly reduced fetal weight (-10%) and significantly increased occurrence of skeletal variations, due to higher rates of fetuses with incomplete ossification of sternebra. No substance-related effects were noted in fetuses from dams receiving 160 or 40 mg/kg per day. NOAEL for maternal toxicity was 40 mg/kg per day; NOAEL for prenatal developmental toxicity was 160 mg/kg per day. No substance-induced teratogenicity was seen up to 640 mg/kg per day. Thus prenatal toxicity was seen at a dose which was severely toxic to the dams. No teratogenic effects were noted at any dose.

The NOAELs for developmental toxicity were very similar in rats (160 mg/kg bw/d) and rabbits (180 mg/kg bw/d). The slight difference is likely due to the differences in the dose level selection between the 2 studies. In the rat study, the only developmental effects observed at the next higher dose level of 640 mg/kg bw/d were reduced fetal weight (-10%) and increased occurrence of skeletal variations. Similar effects were also observed in the rabbit study at the next higher dose level of 540 mg/kg bw/d indicating comparable sensitivity of the two species. Hence, the NOAEL from the rabbit study is taken as key value for this endpoint.

The following information is taken into account for any hazard / risk assessment:

GLP-studies according to OECD guideline 414 using oral gavage administration have been conducted with phenoxypropanol in rats and in rabbits.

Value used for CSA (route: oral): NOAEL: 180 mg/kg bw/day

Toxicity to reproduction: other studies

In a 28 -day dermally toxicity study in rabbits no toxicity to reproductive organs was evident based on organ weights, gross observation, or microscopic examination.

The following information is taken into account for any hazard / risk assessment:

A GLP-study according to OECD guideline 410 in rabbits is available for phenoxypropanol

Justification for classification or non classification

Phenoxypropanol did not produce any developmental effects in the absence of maternal toxicity in rats and rabbits. No effects on fertility were observed in a 2-generation study in rats. Hence, no classification for reproductive toxicity is required for phenoxypropanol.

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

This information is not available.

5.10.1.2. Immunotoxicity

This information is not available.

5.10.1.3. Specific investigations: other studies

This information is not available.

5.10.2. Human information

No human data available.

5.10.3. Summary and discussion of specific investigations

Not applicable.

5.11. Derivation of DNEL(s) / DMEL(s)

5.11.1. Overview of typical dose descriptors for all endpoints

Table 31. Available dose-descriptor(s) per endpoint for the submission substance as a result of its hazard assessment

Endpoint		Dose descriptor	Qualitative assessment	Remarks on study
Acute toxicity	oral	LD50: 2830 mg/kg bw		Non-GLP studies equivalent or similar to OECD guidelines 401 and 402 as well as GLP-studies according to OECD guidelines 402 and 403 are available for phenoxypropanol.
Acute toxicity	dermal	LD50: 2000 mg/kg bw		
Acute toxicity	inhalation	LC50: 5400 mg/m³ air		
Irritation / Corrosivity	skin		not irritating	A GLP study according to OECD guideline 404 and two GLP-studies according to OECD guideline 405 are available for phenoxypropanol.
Irritation / Corrosivity	eye		irritating	
Irritation / Corrosivity	respiratory tract			
Sensitisation	skin		not sensitising	Two GLP-studies according to OECD guideline 406 (Buehler and Maximization test) are available for phenoxyproppanol.
Sensitisation	respiratory tract		not sensitising	No data on respiratory sensitization is available for phenoxypropanol.
Repeated dose toxicity: sub-acute / sub-chronic / chronic	oral	NOAEL: 146 mg/kg bw/day (subchronic; rat) Target organs: urogenital: kidneys		Two repeated dose dermal toxicity studies (14-days and 28-days) in rabbits are available for phenoxypropanol. Both studies have been conduced under GLP and are equivalent or similar to OECD guideline 410. For the oral route 3 GLP-studies according to OECD guidelines 407, 408 and 416 have been conducted in rats using drinking water administration of the test material.
Repeated dose toxicity: sub-acute / sub-chronic / chronic	dermal	NOAEL: 1000 mg/kg bw/day (subacute; rabbit)		
Repeated dose toxicity: sub-acute / sub-chronic / chronic	inhalation			

Mutagenicity	in vitro / in vivo		Genetic toxicity: negative	GLP studies according to OECD guidelines 471, 473, 476 and 474 are available for phenoxpropanol.
Reproductive toxicity: fertility impairment	oral	NOAEL: 477.5 mg/kg bw/day		A GLP-study according to OECD guideline 416 - conducted in rats - is available for phenoxypropanol. The test material was administered via the drinking water.
Reproductive toxicity: fertility impairment	dermal			
Reproductive toxicity: fertility impairment	inhalation			
Reproductive toxicity: developmental toxicity	oral	NOAEL: 180 mg/kg bw/day		GLP-studies according to OECD guideline 414 using oral gavage administration have been conducted with phenoxypropanol in rats and in rabbits.
Reproductive toxicity: developmental toxicity	dermal			
Reproductive toxicity: developmental toxicity	inhalation			

5.11.2. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptor for critical health effects

Table 32. DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal					The substance is not classified for acute dermal toxicity.
Acute - systemic effects	Inhalation					The substance is not classified for acute inhalation toxicity.
Acute - local effects	Dermal	No-threshold effect and/or no dose-response information available				
Acute - local effects	Inhalation	No-threshold effect and/or no dose-response information available				
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	42 mg/kg bw/day	NOAEL: 1,008 mg/kg bw/day (based on AF of 24)	repeated dose toxicity	See discussion below.
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	25.7 mg/m³	NOAEC: 128.5 mg/m³ (based on AF of 5)	repeated dose toxicity	See discussion below.
Long-term - local effects	Dermal	No-threshold effect and/or no dose-response information available				
Long-term - local effects	Inhalation	No-threshold effect and/or no dose-response information available				

**) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.*

Discussion

No DNELs for acute exposure have been derived for phenoxypropanol (PPh) as this substance is not classified for acute toxicity by any route and no acute effects have been observed in the repeated exposure studies. Phenoxypropanol did not show any adverse effects regarding sensitisation, mutagenicity or reproductive toxicity. Therefore, no DNELs have been derived for these endpoints. No DNELs have been derived for local effects as no quantitative assessment is possible due to the lack of dose-response data for skin- and eye-irritation.

Worker-DNEL long-term for the inhalation route:

Phenoxypropanol has a very low vapour pressure (0.002 kPa at 20°C) and has a boiling point of 243°C. Therefore, it is highly unlikely that exposure of workers occurs via the inhalation route. Aerosol formation could be possible under conditions of elevated temperature. No vapour or aerosol inhalation toxicity studies have been conducted with PPh. Therefore, the NOAEL of 146 mg/kg bw/day from the 90-day oral study in rats has been used as the critical dose descriptor to derive the DNEL for inhalation exposure. The systemic NOAEL has been converted into an inhalation concentration of 129 mg/m^3. An intra-species factor of 5 (according to the ECHA Guidance Document, Chapter R.8) has been applied to derive a DNEL long-term for the inhalation route of exposure of 25.7 mg/m^3. No interspecies factor for remaining differences has been applied. According to the ECETOC report (2010) on DNEL derivation the factor for remaining differences is already covered by the allometric factor and the factor for intra-species differences. This is supported by the results of the ERASM project (Mangelsdorf et al 2010) which indicates that no additional factor for remaining differences is justified. No assessment factor has been applied for exposure duration as three repeated dose studies are available for the oral route which showed similar effects and resulted in similar NOAELs. As no significant difference was observed in the NOAELs from the 28-day to the 90-day oral study, no change of the NOAEL is expected going from sub-chronic to chronic exposure. The ECETOC report (2010) on DNEL derivation concludes that - for chemicals with a short half-life - the extension of the exposure duration to more than 28 days is unlikely to have a significant effect on the NOAEL.

Worker-DNEL long-term for the dermal route:

The relevant dose descriptor for long-term exposure via the dermal route is the NOAEL of 1000 mg/kg bw/day from a 28-day dermal toxicity study in rabbits. A total assessment factor of 24, based on the allometric factor of 2.4, the intra-species factor of 5 (according to the ECHA Guidance Document, Chapter R.8) and a factor of 2 for duration of the study has been applied to derive a DNEL long-term for the dermal route of exposure of 42 mg/kg bw/day. No interspecies factor for remaining differences has been applied. According to the ECETOC report (2010) on DNEL derivation the factor for remaining differences is already covered by the allometric factor and the factor for intra-species differences. This is supported by the results of the ERASM project (Mangelsdorf et al 2010) which indicates that no additional factor for remaining differences is justified. A reduced assessment factor of 2 has been applied for exposure duration as two repeated dose studies via the dermal route are available for PPh (14-day and 28-day study) and both studies have shown similar effects and the same NOAEL. As no difference was observed in the NOAEL from the 14-day to the 28-day study, no change of the NOAEL is expected going from sub-acute to chronic exposure. The ECETOC report (2010) on DNEL derivation concludes that - for chemicals with a short half-life - the extension of the exposure duration to more than 28 days is unlikely to have a significant effect on the NOAEL. The ERASM project (Mangelsdorf et al 2010) has identified equivalent extrapolation factors for extrapolation from sub-acute to sub-chronic studies and sub-chronic to chronic studies.

Table 33. DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal					The substance is not classified for acute dermal toxicity.
Acute - systemic effects	Inhalation					The substance is not classified for acute inhalation toxicity.
Acute - systemic effects	Oral					The substance is not classified for acute oral toxicity.
Acute - local effects	Dermal	No-threshold effect and/or no dose-response information available				
Acute - local effects	Inhalation	No-threshold effect and/or no dose-response information available				
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	21 mg/kg bw/day	NOAEL: 1,008 mg/kg bw/day (based on AF of 48)	repeated dose toxicity	See discussion below.
Long-term - systemic effects	Inhalation					See discussion below.
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	3.65 mg/kg bw/day	NOAEL: 146.00 mg/kg bw/day (based on AF of 40)	repeated dose toxicity	See discussion below.
Long-term - local effects	Dermal	No-threshold effect and/or no dose-response information available				
Long-term - local effects	Inhalation	No-threshold effect and/or no dose-response information available				

**) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided*

in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.

Discussion

No DNELs for acute exposure have been derived for phenoxypropanol (PPh) as this substance is not classified for acute toxicity by any route and no acute effects have been observed in the repeated exposure studies. Phenoxypropanol did not show any adverse effects regarding sensitisation, mutagenicity or reproductive toxicity. Therefore, no DNELs have been derived for these endpoints. No DNELs have been derived for local effects as no quantitative assessment is possible due to the lack of dose-response data for skin- and eye-irritation.

General population-DNEL long-term for inhalation route:

Phenoxypropanol has a very low vapour pressure (0.002 kPa at 20°C) and has a boiling point of 243°C. Therefore, it is highly unlikely that exposure occurs via the inhalation route. Aerosol formation could be possible under conditions of elevated temperature. However, no consumer uses of PPh under these conditions are known to us. No vapour or aerosol inhalation toxicity studies have been conducted with PPh and no DNEL for the inhalation route has been derived as inhalation exposure to PPh is unlikely.

General population-DNEL long-term for dermal route:

The relevant dose descriptor for long-term exposure via the dermal route is the NOAEL of 1000 mg/kg bw/day from a 28-day dermal toxicity study in rabbits. A total assessment factor of 48, based on the allometric factor of 2.4, the intra-species factor of 10 (according to the ECHA Guidance Document, Chapter R.8) and a factor of 2 for duration of the study has been applied to derive a DNEL long-term for the dermal route of exposure of 21 mg/kg bw/day. No interspecies factor for remaining differences has been applied. According to the ECETOC report (2010) on DNEL derivation the factor for remaining differences is already covered by the allometric factor and the factor for intra-species differences. This is supported by the results of the ERASM project (Mangelsdorf et al 2010) which indicates that no additional factor for remaining differences is justified. A reduced assessment factor of 2 has been applied for exposure duration as two repeated dose studies via the dermal route are available for PPh (14-day and 28-day study) and both studies have shown similar effects and the same NOAEL. As no difference was observed in the NOAEL from the 14-day to the 28-day study, no change of the NOAEL is expected going from sub-acute to chronic exposure. The ECETOC report (2010) on DNEL derivation concludes that - for chemicals with a short half-life - the extension of the exposure duration to more than 28 days is unlikely to have a significant effect on the NOAEL. The ERASM project (Mangelsdorf et al 2010) has identified equivalent extrapolation factors for extrapolation from sub-acute to sub-chronic studies and sub-chronic to chronic studies.

General population-DNEL long-term for oral route:

The relevant dose descriptor for long-term exposure via the oral route is the NOAEL of 146 mg/kg bw/day from a 90-day drinking water study in rats. A total assessment factor of 40, based on the allometric factor of 4 and the intra-species factor of 10 (according to the ECHA Guidance Document, Chapter R.8) has been applied to derive a DNEL long-term for the oral route of exposure of 3.65 mg/kg bw/day. No interspecies factor for remaining differences has been applied. According to the ECETOC report (2010) on DNEL derivation the factor for remaining differences is already covered by the allometric factor and the factor for intra-species differences. This is supported by the results of the ERASM project (Mangelsdorf et al 2010) which indicates that no additional factor for remaining differences is justified. No assessment factor has been applied for exposure duration as three repeated dose studies are available for the oral route which showed similar effects and resulted in similar NOAELs. As no significant difference was observed in the NOAELs from the 28-day to the 90-day oral study, no change of the NOAEL is expected going from sub-chronic to chronic exposure. The ECETOC report (2010) on DNEL derivation concludes that - for chemicals with a short half-life - the extension of the exposure duration to more than 28 days is unlikely to have a significant effect on the NOAEL.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1. Explosivity

Data waiving: see CSR section 1.3 Physico-chemical properties.

The following information is taken into account for any hazard / risk assessment:

1-Phenoxypropan-2-ol (propylene glycol phenyl ether) does not contain chemically unstable or highly energetic groups like those mentioned in table R.7.1-28 (ECHA Guidance, 2008). Therefore the substance is determined to be not explosive.

Classification according to GHS

Name: 1-phenoxypropan-2-ol

State/form of the substance: liquid

Reason for no classification: conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (Phenoxypropanol)

Reason for no classification: conclusive but not sufficient for classification

6.2. Flammability

The available information on flammability is summarised in the following table:

Table 34. Overview of information on flammability

Method	Results	Remarks	Reference
Method: calculation	Evaluation of results: non flammable Study results: Ignition on contact with air: no Lower explosion limit (%): ca. 0.8 (mol% (calculated))	2 (reliable with restrictions) key study estimated by calculation **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1996)
closed cup EU Method A.9 (Flash-Point)	Flash point: ca. 239 °F at ca. 760 mm Hg	2 (reliable with restrictions) key study experimental result **Test material (EC name): 1-phenoxypropan-2-**	The Dow Chemical Company (2007)

		ol	
closed cup EU Method A.9 (Flash-Point)	Flash point: ca. 119.5 °C at ca. 1013 hPa	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1987)
Determination of flash point closed cup Method not reported.	Flash point: 120 °C	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	D. Stoye
Determination of flash point open cup	Flash point: 129 °C	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	Canadian Centre for Occupational Health and Safety (2001)

The following information is taken into account for any hazard / risk assessment:

1-Phenoxypropan-2-ol (propylene glycol phenyl ether) is not classified for flammability according to EU criteria.

Flash point

The following information is taken into account for any hazard / risk assessment:

The flash point of 1-phenoxypropan-2-ol is 115 °C (239 °F) at atmospheric pressure.

Classification according to GHS

Name: 1-phenoxypropan-2-ol

State/form of the substance: liquid

Reason for no classification (Flammable gases): conclusive but not sufficient for classification

Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification

Reason for no classification (Flammable solids): conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (Phenoxypropanol)

Reason for no classification: conclusive but not sufficient for classification

Justification for classification or non-classification:

1-Phenoxypropan-2-ol (propylene glycol phenyl ether) has a flash point greater than 60 °C (115 °C) and a boiling point greater than 35 °C (241 °C). Therefore no classification for flammability according to EU DSD and CLP criteria is required.

6.3. Oxidising potential

Data waiving: see CSR section 1.3 Physico-chemical properties.

In accordance with column 2 of REACH Annex VII, the study does not need to be conducted if the substance is incapable or reacting exothermically with combustible materials. 1-Phenoxypropan-2-ol (propylene glycol phenyl ether) is a saturated glycol ether with no functional and chemical groups associated with oxidising properties. 1-Phenoxypropan-2-ol (propylene glycol phenyl ether) has no oxidising character. With the absence of structural alerts, classification for oxidizing properties is not required.

The following information is taken into account for any hazard / risk assessment:

1-Phenoxypropan-2-ol (propylene glycol methyl ether) is not an oxidizing substance according to the ECHA guidance "Guidance on information requirements and chemical safety assessment, Chapter R.7a: Endpoint specific guidance, Mai 2008). 1-Phenoxypropan-2-ol (propylene glycol methyl ether) does not contain chemical groups associated with oxidising properties. With the absence of structural alerts testing is not necessary.

Classification according to GHS

Name: 1-phenoxypropan-2-ol

State/form of the substance: liquid

Reason for no classification (Oxidising gases): conclusive but not sufficient for classification

Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification

Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (Phenoxypropanol)

Reason for no classification: conclusive but not sufficient for classification

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.1.1. Toxicity test results

Acute toxicity studies have been conducted in fish, daphnia and algae. The EC50s/LC50s for propylene glycol phenyl ether is 280 mg/L for fish (Fathead minnow), 370mg/L for Daphnia and >100 mg/L in algae, while the algal NOEC was 55.5 mg/L. Since 42.7% inhibition of the growth rate was observed at the highest tested concentration of 100 mg/L, this concentration will be considered as a conservative estimation of the algal EC50, which indicates that alga was the most sensitive species tested. This value will therefore be used in the PNEC derivation. The EC50 determined in a respiration inhibition test according is greater than 1000mg/L. Propylene glycol phenyl ether is readily biodegradable and has very low potential for bioaccumulation (log Kow <2). According to REACH Annex IX requirements, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations. Hence, long-term testing in aquatic species (fish and invertebrate) can be waived.

7.1.1.1. Fish

7.1.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 35. Overview of short-term effects on fish

Method	Results	Remarks	Reference
Pimephales promelas freshwater static equivalent or similar to OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96 h): 280 mg/L test mat. (nominal)	2 (reliable with restrictions) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company. (1978)
Leuciscus idus freshwater static DIN 38412	LC50 (96 h): 215 — 464 mg/L	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1988)

Discussion

The LC50 for propylene glycol phenyl ether was 280mg/L in Fathead minnow and between 215 and 464 mg/L in the Golden orfe. The results of both tests are consistent. Nevertheless, the range of test concentrations chosen for the Fathead minnow test allowed a more accurate determination of the LC50, hence the latter is selected as a key study for this endpoint.

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

Two non-GLP studies similar to OECD guideline 203 are available.

Value used for CSA:

LC50 for freshwater fish: 280 mg/L

7.1.1.1.2. Long-term toxicity to fish

Data waiving

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is classified as readily biodegradable, therefore no long-term exposure to aquatic species is expected. The risk assessment shows that the PEC/PNEC ratio is clearly < 1 in surface water, indicating no need for further information or testing. According to REACH Annex IX requirements, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations. Hence, long-term testing in aquatic species (fish) can be waived.

Discussion

Propylene glycol phenyl ether is classified as readily biodegradable, therefore no long-term exposure to aquatic species is expected. The risk assessment shows that the PEC/PNEC ratio is clearly < 1 in surface water, indicating no need for further information or testing. According to REACH Annex IX requirements, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations. Hence, long-term testing in aquatic species (fish) can be waived.

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

No studies on the chronic toxicity to fish are available.

7.1.1.2. Aquatic invertebrates

7.1.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 36. Overview of short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna freshwater static equivalent or similar to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	LC50 (24 h): 471 mg/L test mat. (nominal) based on: mortality LC50 (48 h): 370 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company. (1978)
Daphnia magna	EC50 (48 h): > 100 mg/L	1 (reliable without	BASF AG (1997b)

freshwater static EU Method C.2 (Acute Toxicity for Daphnia)	test mat. (nominal) based on: mobility	restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	

Discussion

The LC50 for propylene glycol phenyl ether is greater than 100 mg/L in Daphnia in the GLP study, as no effects were observed at the highest test concentration (BASF, 1997). The EC50 determined in a second study on Daphnia was determined at 370 mg/L (Dow, 1978). Since the results of both studies are consistent, the latter EC50 is selected as a key study for this endpoint.

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

A GLP studies according to guideline EU Method C.2 (Acute Toxicity for Daphnia) and a non-GLP study according to a test protocol similar to OECD 202 are available.

Value used for CSA:

EC50/LC50 for freshwater invertebrates: 370

7.1.1.2.2. Long-term toxicity to aquatic invertebrates

Data waiving

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is classified as readily biodegradable, therefore no long-term exposure to aquatic species is expected. The risk assessment shows that the PEC/PNEC ratio is clearly < 1 in surface water, indicating no need for further information or testing. According to REACH Annex IX requirements, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations. Hence, long-term testing in aquatic species (inverterbrate) can be waived.

Discussion

Propylene glycol phenyl ether is classified as readily biodegradable, therefore no long-term exposure to aquatic species is expected. The risk assessment shows that the PEC/PNEC ratio is clearly < 1 in surface water, indicating no need for further information or testing. According to REACH Annex IX requirements, long-term toxicity testing shall only be considered when the chemical safety assessment indicates the need for further investigations. Hence, long-term testing in aquatic species (inverterbrate) can be waived.

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

No studies on the chronic toxicity to inverterbrate are available.

7.1.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 37. Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference
Scenedesmus subspicatus (new name: Desmodesmus subspicatus) (algae) freshwater static EU Method C.3 (Algal Inhibition test) (Cited as Directive 92/69/EEC, C.3)	EC50 (72 h): > 100 mg/L test mat. (nominal) based on: growth rate NOEC (72 h): 12.5 mg/L test mat. (nominal) based on: growth rate LOEC (72 h): 25 mg/L test mat. (nominal) based on: growth rate EC10 (72 h): 55.5 mg/L test mat. (nominal) based on: growth rate	1 (reliable without restriction) key study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	BASF AG (1997c)

Discussion

Effects on algae / cyanobacteria

The growth rate EC50 for propylene glycol phenyl ether is greater than 100 mg/L in Scenedesmus subspicatus, while the NOEC is12.5 mg/L. Since 42.7% inhibition of the growth rate was observed at the highest tested concentration of 100 mg/L, this concentration will be considered as a conservative estimation of the algal EC50, which indicates that alga was the most sensitive species tested.

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

A GLP OECD 201 study is available.

Value used for CSA:

EC50/LC50 for freshwater algae: 100 mg/L

7.1.1.4. Sediment organisms

Data waiving

Reason: exposure considerations

Justification: According to REACH Annex IX requirements, sediment simulation testing shall only be considered for substances with a high potential for adsorption to sediment. Further, the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of sediment is unlikely. Propylene glycol phenyl ether is readily biodegradable in freshwater with a low potential for adsorption to sediment (Kow<3), hence a simulation test in water and sediment can be waived.

Discussion

According to REACH Annex IX requirements, sediment simulation testing shall only be considered for substances with a high potential for adsorption to sediment. Further, the study does not need to be conducted if the substance is readily biodegradable or if direct and indirect exposure of sediment is unlikely. Propylene glycol phenyl ether is readily biodegradable in freshwater with a low potential for adsorption to sediment (Kow<3), hence a simulation test in water and sediment can be waived.

The following information is taken into account for sediment toxicity for the derivation of PNEC:

No studies on sediment organisms are available for propylene glycol phenyl ether.

7.1.1.5. Other aquatic organisms

This information is not available.

7.1.2. Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1. PNEC water

Table 38. PNEC water

PNEC	Assessment factor	Remarks/Justification
PNEC aqua (freshwater): 0.1 mg/L	1000	Extrapolation method: assessment factor The EC50s/LC50s for propylene glycol phenyl ether is 280 mg/L for fish (Fathead minnow), 370mg/L for Daphnia and >100 mg/L in algae, while the algal NOEC was 55.5 mg/L. Since 42.7% inhibition of the growth rate was observed at the highest tested concentration of 100 mg/L, this concentration will be considered as a conservative estimation of the algal EC50, which indicates that alga was the most sensitive species tested. According to Chapter R:10: Characterization of dose (concentration)-response for the environment, the PNEC should be derived from the lowest acute toxicity value (algal EC50=100mg/L) with an assessment factor of 1000.
PNEC aqua (marine water): 0.01 mg/L	10000	Extrapolation method: assessment factor The EC50s/LC50s for propylene glycol phenyl ether is 280 mg/L for fish (Fathead minnow), 370mg/L for Daphnia and >100 mg/L in algae, while the algal NOEC was 55.5 mg/L. Since 42.7% inhibition of the growth rate was observed at the highest tested concentration of 100 mg/L, this concentration will be considered as a conservative estimation of the algal EC50, which indicates that alga was the most sensitive species tested. According to Chapter R:10: Characterization of dose (concentration)-response for the environment, the PNEC should be derived from the lowest acute toxicity value (algal EC50=100mg/L) with an assessment factor of 10000.
PNEC aqua (intermittent releases): 1 mg/L	100	Extrapolation method: assessment factor The EC50s/LC50s for propylene glycol phenyl ether is 280 mg/L for fish (Fathead minnow), 370mg/L for Daphnia and >100 mg/L in algae, while the algal NOEC was 55.5 mg/L. Since 42.7% inhibition of the growth

		rate was observed at the highest tested concentration of 100 mg/L, this concentration will be considered as a conservative estimation of the algal EC50, which indicates that alga was the most sensitive species tested. According to Chapter R:10: Characterization of dose (concentration)-response for the environment, the PNEC should be derived from the lowest acute toxicity value (algal EC50=100mg/L) with an assessment factor of 100.

7.1.2.2. PNEC sediment

Table 39. PNEC sediment

PNEC	Assessment factor	Remarks/Justification
PNEC sediment (freshwater): 0.38 mg/kg sediment dw		Extrapolation method: partition coefficient The PNECsediment was calculated using the equilibrium partitioning method, as recommended in the Technical Guidance document (ECHA, 2008), in the absence of experimental data on sediment dwellers. The PNEC sediment of 0.08 mg/kg wwt was derived from the freshwater PNEC=0.1 mg/L and the measured Koc = 1.55L/kg. Based on a moisture content of 78.3 % of the standard sediment, the PNEC sediment for a dry sediment was calculated to 0.38 mg/kg dwt.
PNEC sediment (marine water): 0.038 mg/kg sediment dw		Extrapolation method: partition coefficient The PNECsediment was calculated using the equilibrium partitioning method, as recommended in the Technical Guidance document (ECHA, 2008), in the absence of experimental data on sediment dwellers. The PNEC sediment of 0.008 mg/kg wwt was derived from the marine PNEC=0.01 mg/L and the measured Koc = 1.55L/kg. Based on a moisture content of 78.3 % of the standard sediment, the PNEC sediment for a dry sediment was calculated to 0.038 mg/kg dwt.

7.2. Terrestrial compartment

7.2.1. Toxicity test results

Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

7.2.1.1. Toxicity to soil macro-organisms

Data waiving

Information requirement: Toxicity to soil macro-organisms except arthropods

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

Information requirement: Toxicity to terrestrial arthropods

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

Discussion of effects on soil macro-organisms except arthropods

Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

No studies on terrestrial organisms are available for propylene glycol phenyl ether.

Discussion of effects on soil arthropods

Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

The following information is taken into account for effects on soil arthropods for the derivation of PNEC:

No studies on terrestrial organisms are available for propylene glycol phenyl ether.

7.2.1.2. Toxicity to terrestrial plants

Data waiving

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

Discussion

Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

No studies on terrestrial organisms are available for propylene glycol phenyl ether.

7.2.1.3. Toxicity to soil micro-organisms

Data waiving

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

Discussion

Propylene glycol phenyl ether is readily biodegradable, highly water soluble and has a very low potential for adsorption to organic matter. Therefore, the predicted no effect concentration (PNEC) for soil was derived from the PNEC for freshwater using the equilibrium partitioning method. This method is applicable for substances where the toxicity in soils relates to the freely dissolved concentration in pore water. According to REACH Annex IX and X requirements (column 2), studies on terrestrial organisms do not need to be conducted, if direct and indirect exposure of the soil compartment is unlikely. The risk characterisation shows that the PEC/PNEC ratio for soil is clearly <1, indicating no need for further information and testing. Hence testing of effects on terrestrial organisms can be waived.

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

No studies on terrestrial organisms are available for propylene glycol phenyl ether.

7.2.1.4. Toxicity to other terrestrial organisms

7.2.2. Calculation of Predicted No Effect Concentration (PNEC soil)

Table 40. PNEC soil

PNEC	Assessment factor	Remarks/Justification
PNEC soil: 0.02 mg/kg soil dw		Extrapolation method: partition coefficient The PNECsoil was calculated using the equilibrium partitioning method, as recommended in the Technical Guidance document (ECHA, 2008), in the absence of experimental data on soil organisms. The PNEC soil of 0.01 mg/kg wwt was derived from the freshwater PNEC= 0.1 mg/L, a measured Koc = 1.55 l/kg and an estimated Henry constant of 0.04 Pa m3/mol (Staples and David, 2002). Based on a moisture content of 11.8 % of the standard soil, the PNEC soil for a dry soil was calculated to 0.02 mg/kg dwt.

7.3. Atmospheric compartment

This information is not available.

7.4. Microbiological activity in sewage treatment systems

7.4.1. Toxicity to aquatic micro-organisms

The results are summarised in the following table:

Table 41. Overview of effects on micro-organisms

Method	Results	Remarks	Reference
activated sludge, domestic freshwater static OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test)	EC50 (30 min): > 1000 mg/L test mat. (nominal) based on: respiration rate	1 (reliable without restriction) key study experimental result **Test material: >>>??? ID missing in IUCLID<<<**	BASF AG (1999b)
activated sludge of a predominantly domestic sewage freshwater static OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test)	EC0 (28 d): mg/L test mat. (nominal) based on: Oxygen consumption	1 (reliable without restriction) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	The Dow Chemical Company (1998d)
other bacteria: Pseudomonas aeruginosa , Escherichia coli, Staphylococcus aureus, Streptococcus faecalis, Bacillus subtilis static Method: other		2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	Clausen OG and Hegna IK (1977)
other bacteria: Pseudomonas aeruginosa SIFF 627, Escherichia coli Sc, Klebsiella sp. SIFF 7550, Proteus mirabilis (API) Sr, Staphylococcus aureus SIFF 1085, Streptococcus faecalis Sc static Method: other		2 (reliable with restrictions) supporting study experimental result **Test material (EC name): 1-phenoxypropan-2-ol**	Hegna IK and Clausen OG (1988)

Discussion

The EC50 determined in a respiration inhibition test according is greater than 1000 mg/L.

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

A OECD 206 respiration inhibition test according to GLP is available.

Value used for CSA:

EC50/LC50 for aquatic micro-organisms: 1000 mg/L

EC10/LC10 or NOEC for aquatic micro-organisms: 40 mg/L

7.4.2. PNEC for sewage treatment plant

Table 42. PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 10 mg/L	100	Extrapolation method: assessment factor The PNEC for micro-organisms was derived from a sewage sludge respiration inhibition test (EC50>1000mg/L) , therefore the PNEC was derived by applying an assessment factor of 100.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

Data waiving

Information requirement: Toxicity to birds

Reason: exposure considerations

Justification: Propylene glycol phenyl ether is readily biodegradable and has very low potential for bioaccumulation (log Kow<2). Secondary poisoning is therefore not considered as relevant route of exposure for birds.

Discussion

Propylene glycol phenyl ether is readily biodegradable and has very low potential for bioaccumulation (log Kow<2). Secondary poisoning is therefore not considered as relevant route of exposure for birds.

The following information is taken into account for effects on birds for the derivation of PNEC:

No studies on the toxicity to birds are available for propylene glycol phenyl ether.

7.5.2. Toxicity to mammals

This information is not available.

7.5.3. Calculation of PNECoral (secondary poisoning)

Table 43. PNEC oral

PNEC	Assessment factor	Remarks/Justification
No potential for bioaccumulation		Propylene glycol phenyl ether is readily biodegradable and has very low potential for bioaccumulation (log Kow <2).

7.6. Conclusion on the environmental hazard assessment and on classification and labelling

Environmental classification justification

According to Chapter 4 VI of Directive 67/548/EEC, no classification is required for propylene glycol phenyl ether, as all EC50 are greater than 100 mg/L.

8. PBT AND VPVB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. Summary and overall conclusions on PBT or vPvB properties

Propylene glycol phenyl ether does not have PBT or vPvB Properties.

8.1.2. PBT/vPvB criteria and justification

Persistence Assessment

Propylene glycol phenyl ether meets the criteria for ready biodegradation, according to the results of a biodegradation screening test according to OECD guideline 301F. At the end of the 10-day window 72% biodegradation were observed. In conclusion, propylene glycol phenyl ether can be considered as readily biodegradable under aerobic conditions. Hence, the test substance does not fulfill the criteria for persistency as outlined in Annex XIII of the REACH legislation of December 2006.

Bioaccumulation Assessment
According to Annex XIII of Regulation (EC) No 1907/2006 and to the Guidance on information requirements and chemical safety assessment Chapter R.11 (PBT Assessment, May 2008), a substance does not fulfill the criterion "bioaccumulative (B)" or "very bioaccumulative (vB)" if the BCF is below 2000 respectively 5000 or the log Kow is below 4.5.

Propylene glycol phenyl ether has a low log Kow (log Kow = 1.4) and is readily biodegradable, which indicates that propylene glycol phenyl ether offers little potential for bioconcentration in aquatic organisms. Therefore it does not fulfill the criteria for bioaccumulation as outlined in Annex XIII of REACH legislation of December 2006.

Toxicity Assessment

According to Annex XIII of Regulation (EC) No 1907/2006 and according to the Guidance on information requirements and chemical safety assessment Chapter 11 (PBT Assessment, May 2008), a substance does not fulfill the criterion if the NOEC for marine or freshwater organisms is higher than 0.01mg/l and if there is no evidence of chronic toxicity considering human health and no classification as carcinogenic (category1 or 2), mutagenic (category 1or 2) or toxic for reproduction (category 1, 2 or 3) according to Directive 67/548/ECC.

Measured aquatic toxicity data indicate that propylene glycol phenyl ether presents a low toxicity hazard to aquatic species. All EC50/LC50 values (fish, daphnia and algae) are greater than 100 mg/l. Propylene glycol phenyl ether is not classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) and there is no evidence of chronic toxicity, as identified by the classifications STOT (repeated exposure), category 1(oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) according to Regulation (EC) No 1272/2008.

8.2. Emission Characterisation

Not applicable

9. EXPOSURE ASSESSMENT

Introduction and uses

Propylene Glycol Phenyl Ether (PPh) is widely used as a solvent in paints, inks, cleaners, degreasers, as a coalescing agent in water based paints and inks and also in coatings for industrial (automotive), professional and consumer use. It is also used as an ingredient in cosmetic products.

The most likely route of human exposure (workers and consumers) to PPh is through inhalation or dermal contact. Worker exposure can occur in PPh manufacturing facilities or the industrial facilities where the substance is used as an intermediate, processing agent and in formulation activities. Since these types of activities are mainly undertaken in closed systems, exposure is fairly low. Higher worker exposures are likely in industrial or professional applications of end products containing the substance (paints, coatings, cleaning agents). To some extent, also consumer exposure can also occur as a result of use of paints, varnishes, cleaners containing PPh. In industrial, professional and consumer uses, releases to the environment occur mostly to the air compartment with lower emissions to the water.

The registrant has conducted a mapping of uses within the supply chain. Information on the uses, the upper use concentration in the products and the related tonnage information for each application have been shared within the consortium. Based on the results of this mapping and using the Generic Exposure Scenarios as a basis (as developed within the solvent sector, ESIG/ESVOC), the following uses (as stated in chapter 2) have been identified:

- IU1: use as chemical intermediate
- IU2: use as process solvent
- IU3: distribution
- IU4: formulation and (re)packing
- IU5: industrial use in coatings (water based)
- IU6: professional use in coatings (solvent based)
- IU7: consumer use in coatings (water based)
- IU8: professional use in cleaning agents
- IU9: consumer use in cleaning agents
- IU10: professional use in metalworking fluids/rolling oils
- IU11: use in cosmetic products

For these identified uses a number of exposure scenarios have been derived, again by taking the Generic Exposure Scenarios (ESIG/ESVOC) as a basis. An overview of exposure scenarios is provided in the table below. With respect to these exposure scenarios the following applies:

- Industrial use as an intermediate in process, solvents for chemical synthesis, and formulation: upper concentrations of PPh are assumed to be 100 % (w/w).
- Industrial use in paints and coatings: upper concentrations of PPh are assumed to be 30 % (w/w) for water based and solvent based paints.
- Professional use in paints, coatings and inks: upper concentrations of PPh are assumed to be 30 % (w/w) for both water based and solvent based paints as for inks.

- Professional use in cleaners: upper concentrations of PPh are assumed to be 10 % (w/w).
- Professional use in metal working fluids/rolling oils: upper concentrations of PPh are assumed to be 10 % (w/w).
- Consumer use in paints and coatings: upper concentrations of PPh are assumed to be 5 % (w/w) for water borne paints and coatings.
- Consumer use in detergents and cleaners: upper concentrations of PPh are assumed to be 5 % (w/w).
- Use in cosmetic products: this use is only relevant regarding environmental exposure; according to article 14 (5b) of the REACH regulation the risks for human health resulting from exposure to cosmetic products within the scope of Directive 76/768/EEC do not need to be taken into account).

ES no	*ES title*	*Linked to IU*	*Sector of Use (SU)*	*Life Cycle Stage*	*Product Category (PC)*	*Process Category (PROC)*	*Article Category (AC)*	*Environmental Release Category (ERC)*	*Tonnage (tonnes)*
ES1	Use as chemical intermediate	IU1	3	EU	NA	1, 2, 3, 4, 8a, 8b, 15	NA	ERC6a	9
ES2	Use as a process solvent	IU2	3	EU	NA	1, 2, 3, 4, 8a, 8b, 15	NA	ERC4	5
ES3	Distribution	IU3	3	FO	NA	1, 2, 3, 4, 8a, 8b, 9, 15	NA	ERC-7	1045
ES4	Formulation and (re)packing	IU4	3	FO	NA	1, 2, 3, 4, 5, 8a, 8b, 9, 14, 15	NA	ERC2	1045
ES5	Industrial use in coatings	IU5	3	EU	NA	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 15	NA	ERC4	313
ES6	Professional use in coatings	IU6	22	EU	NA	1, 2, 3, 4, 5, 8a, 8b, 9, 10, 11, 13, 15, 19	NA	ERC8A, 8D	16
ES7	Consumer use in coatings (water based)	IU7	21	CU	PC9a	NA	NA	ERC8A, 8D	17
ES8	Professional use in cleaning agents	IU8	22	EU	NA	1, 2, 3, 4, 8a, 8b, 10,13	NA	ERC8A, 8D	110
ES9	Consumer use in cleaning agents	IU9	21	CU	PC35	NA	NA	ERC8A, 8D	110
ES10	Professional use in metal working fluids/rolling oils	IU10	22	EU	NA	1, 2, 4, 8a, 8b, 9, 10 11, 13, 17	NA	ERC8A, 8D	210
ES11	Use in cosmetics (environment)	IU11	21	EU	NA	NA	NA	ERC8A,	50

The following information has been used for the exposure assessments:

Substance	PPh
CAS no	770-35-4
Substance Volatility (Pa at 20 ° C)	2
TRA Volatility Range	low
Biodegradability	readily biodegradable
Molecular Weight (g/mol)	152.19
Melting Point (° C)	11
Boiling Point (° C)	241.2
Solubility (g/l at 20 ° C)	15.1
Kow	1.41
Chemical class for Koc-QSAR	non-hydrophobic
Koc L/kg	1.55
Koc	1

Remarks on worker assessment:

Note: where in the worker risk assessment use of gloves (tested to EN374) is advised, the following chemically resistant glove materials should be used:

- Preferred glove materials: Butyl rubber; Ethyl vinyl alcohol laminate ("EVAL").
- Acceptable glove materials: Viton; Neoprene; Natural rubber (latex); Polyvinyl chloride ("PVC" or "vinyl"); Nitrile/butadiene rubber ("nitrile" or "NBR").
- prolonged or frequently repeated contact: glove material with a protection class of 4 or higher (breakthrough time greater than 120 minutes according to EN 374)
- brief contact: glove material with a protection class of 1 or higher (breakthrough time greater than 10 minutes according to EN 374)

9.1. Exposure scenario 1: Use as an intermediate

This scenario addresses the use of the substance as an intermediate, resulting in full consumption of the substance in the synthesis process.

9.1.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Use as an intermediate**
Sector of Use	SU3
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC15
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC6A
Specific environmental release category	ESVOC 2, ESVOC SpERC 6.1a.v1
Processes, tasks, activities covered	Use of substance as an intermediate (not related to Strictly Controlled Conditions). Includes recycling/ recovery, material transfers, storage, sampling, associated laboratory activities, maintenance and loading (including marine vessel/barge, road/rail car and bulk container).
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 100%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
Identifier*	***Contributing Scenarios***	***Process Categories***	***Risk Management Measures***
ES1-W1	General exposures [CS1]. ; Continuous process [CS54]. ; (closed systems) [CS107]	1	No other specific measures identified [EI20].
ES1-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES1-W3	Use in contained batch processes [CS37].	3	No other specific measures identified [EI20].
ES1-W4	General exposures (open systems) [CS16].	4	Provide extract ventilation to points where emissions occur [E54].
ES1-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES1-W6a	Equipment cleaning and maintenance [CS39].	8a	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 1 hour [OC27].
ES1-W6b	Equipment cleaning and maintenance [CS39].	8a	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]
ES1-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 4 hours [OC28].
ES1-W8	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES1-W9	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

Section 2	**Operational conditions and risk management measures**
Section 2.2	**Control of environmental exposure**
Identifier	ES1-E1
Contributing scenario	Use as an intermediate
Environmental Release Category	ERC6a
Specific ERC	ESVOC 2, ESVOC SpERC 6.1a.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	9

Fraction of EU tonnage used in region	1
Fraction of main source to local environment	1
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	30
Frequency and duration of use	
Type of release	continuous
Emission days (days/year)	300
Site specific monitoring data results for surface water effluent	Not applicable
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	
Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations.
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	Vapour recovery units should be used when necessary.

9.1.2. Exposure estimation

9.1.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:
Fugacity: low
Type of Use; industrial
Concentration: > 25 %
Local Exhaust Ventilation: none
Duration of Exposure: > 4 hours/day

Respiratory Protection Equipment: none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

*Identifier**	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES1-W1	General exposures [CS1]. ; Continuous process [CS54]. ; (closed systems) [CS107]	1	No other specific measures identified [EI20].	0.06	n.a.	0.34	n.a.	n.a.
ES1-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES1-W3	Use in contained batch processes [CS37].	3	No other specific measures identified [EI20].	19.03	n.a.	0.34	n.a.	n.a.
ES1-W4	General exposures (open systems) [CS16].	4	Provide extract ventilation to points where emissions occur [E54].	3.17	n.a.	6.86	n.a.	n.a.
ES1-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	0.34	n.a.	n.a.
ES1-W6a	Equipment cleaning and maintenance [CS39].	8a	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 1 hour [OC27].	8.88	n.a.	13.71	n.a.	n.a.
ES1-W6b	Equipment cleaning and maintenance [CS39].	8a	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]	6.34	n.a.	13.71	n.a.	n.a.

ES1-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 4 hours [OC28].	13.32	n.a.	6.86	n.a.	n.a.
ES1-W8	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES1-W9	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]	22.20	n.a.	0.34	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

9.1.2.2. Consumer exposure

Not applicable.

9.1.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.1.2.4. Environmental exposure

Identifier	*ES1-E1*
Narrative	Release fraction were estimated with ESVOC 2, ESVOC SpERC 6.1a.v1
Release fraction to air from process	0.002
Release fraction to wastewater from process	3.00E-04

Release fraction to soil from process (regional only)	1.00E-03
Local release to air (kg/d)	6.00E-03
Local release to sewage (kg/d)	0.0009
Local release to soil (kg/d)	0.003
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	Not applicable
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	167325
Scaling	
The downstream user can check the compliance of his site by comparing site specific data with defaults used in the exposure assessment. The site specific quotient should be inferior or equal to the spERC quotient.	Not applicable as the exposure is generic and applies to the largest manufacturing capacity

$$\frac{m_{Safe} * (1 - E_{ER}) F^*_{release}}{DF} \geq \frac{m_{site} * (1 - E_{ER,site}) F^*_{release,site}}{DF_{site}}$$

m_{safe} Susbstance use rate in scenario (kg/d)
$E_{ER,spERC}$: Efficacy of RMM in scenario (-)
$F_{release\_spERC}$: Initial release fraction in scenario (-)
DF: dilution factor of STP effluent in river

m_{site}: Susbstance use rate at site (kg/d)
$E_{ER,site}$: Efficacy of RMM at site (-)
$F_{release\_site}$: Initial release fraction at site (-)
DF_{site}: dilution factor of STP effluent in river (-)

9.1.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES1-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	1.79E-05
Annual average local PEC in surface water (dissolved)	mg/L	1.50E-05
Local PEC in fresh water sediment during emission episode	mg/kg dwt	6.74E-05
Local PEC in sea water during emission episode	mg/L	1.77E-06
Annual average local PEC in sea water (dissolved)	mg/L	1.48E-06
Local PEC in marine sediment during emission episode	mg/kg dwt	6.65E-06
PEC for microorganisms in STP	mg/L	1.64E-04
Comments		

9.1.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	ES1-E1
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	5.12E-08

Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	2.51E-08
Local PEC in grass land, averaged over 180 days	mg/kg dwt	2.37E-08
Comments		

9.1.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES1-E1*
Annual average local PEC in air (total)	mg/m^3	1.75E-05

9.1.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.2. Exposure scenario 2: Use as a process solvent

This scenario addresses the use of the substance as process solvent.

9.2.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Use as a process solvent**
Sector of Use	SU3
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC15
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC4
Specific environmental release category	ESVOC 43, ESVOC SpERC 4.20.v1
Processes, tasks, activities covered	Use as a process chemical or extraction agent. Includes recycling/ recovery, material transfers, storage, sampling, associated laboratory activities, maintenance and loading (including marine vessel/barge, road/rail car and bulk container).
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 100%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
*Identifier**	*Contributing Scenarios*	*Process Categories*	*Risk Management Measures*
ES2-W1	General exposures [CS1]. ; Continuous process [CS54]. ; (closed systems) [CS107]	1	No other specific measures identified [EI20].
ES2-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES2-W3	Use in contained batch processes [CS37].	3	No other specific measures identified [EI20].
ES2-W4	General exposures (open systems) [CS16].	4	Provide extract ventilation to points where emissions occur [E54].
ES2-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES2-W6a	Equipment cleaning and maintenance [CS39].	8a	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 1 hour [OC27].
ES2-W6b	Equipment cleaning and maintenance [CS39].	8a	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]
ES2-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 4 hours [OC28].
ES2-W8	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES2-W9	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

Section 2	Operational conditions and risk management measures
Section 2.2	**Control of environmental exposure**
Identifier	ES2-E1
Contributing scenario	Process solvent
Environmental Release Category	ERC4
Specific ERC	ESVOC 43, ESVOC SpERC 4.20.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	5
Fraction of EU tonnage used in region	1
Fraction of main source to local environment	1
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	17
Frequency and duration of use	
Type of release	continuous
Emission days (days/year)	300
Site specific monitoring data results for surface water effluent	
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Treat air emissions to provide a typical removal efficiency of (%)	
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	Not applicable
Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations.
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	Vapour recovery units should be used when necessary.

9.2.2. Exposure estimation

9.2.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	industrial
Concentration:	> 25 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

Identifier	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES2-W1	General exposures [CS1]. ; Continuous process [CS54]. ; (closed systems) [CS107]	1	No other specific measures identified [EI20].	0.06	n.a.	0.34	n.a.	n.a.
ES2-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES2-W3	Use in contained batch processes [CS37].	3	No other specific measures identified [EI20].	19.03	n.a.	0.34	n.a.	n.a.
ES2-W4	General exposures (open systems) [CS16].	4	Provide extract ventilation to points where emissions occur [E54].	3.17	n.a.	6.86	n.a.	n.a.
ES2-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	0.34	n.a.	n.a.
ES2-W6a	Equipment cleaning and maintenance [CS39].	8a	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 1 hour [OC27].	8.88	n.a.	13.71	n.a.	n.a.

ES2-W6b	Equipment cleaning and maintenance [CS39].	8a	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]	6.34	n.a.	13.71	n.a.	n.a.
ES2-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or: Ensure operation is undertaken outdoors [E69]. Avoid carrying out activities involving exposure for more than 4 hours [OC28].	13.32	n.a.	6.86	n.a.	n.a.
ES2-W8	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES2-W9	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]	22.20	n.a.	0.34	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

9.2.2.2. Consumer exposure

Not applicable.

9.2.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.2.2.4. Environmental exposure

Identifier	*ES2-E1*
Narrative	Release fraction were estimated with ESVOC 43, ESVOC SpERC 4.20.v1
Release fraction to air from process	0.002
Release fraction to wastewater from process	3.00E-04
Release fraction to soil from process (regional only)	1.00E-04
Local release to air (kg/d)	3.33E-02
Local release to sewage (kg/d)	5.00E-03
Local release to soil (kg/d)	1.67E-04
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	156400
Scaling	
The downstream user can check the compliance of his site by comparing site specific data with defaults used in the exposure assessment. The site specific quotient should be inferior or equal to the spERC quotient.	Not applicable as the exposure is generic and applies to the largest manufacturing capacity

$$\frac{m_{Safe} * (1 - E_{ER}) F^*_{release}}{DF} \geq \frac{m_{site} * (1 - E_{ER,site}) F^*_{release,site}}{DF_{site}}$$

m_{safe} Susbstance use rate in scenario (kg/d)
$E_{ER,spERC}$: Efficacy of RMM in scenario (-)
$F_{release,spERC}$: Initial release fraction in scenario (-)
DF: dilution factor of STP effluent in river

m_{site}: Susbstance use rate at site (kg/d)
$E_{ER,site}$: Efficacy of RMM at site (-)
$F_{release,site}$: Initial release fraction at site (-)
DF_{site}: dilution factor of STP effluent in river (-)

9.2.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES2-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	1.07E-05
Annual average local PEC in surface water (dissolved)	mg/L	9.04E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	4.00E-05
Local PEC in sea water during emission episode	mg/L	1.04E-06
Annual average local PEC in sea water (dissolved)	mg/L	8.80E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	3.91E-06
PEC for microorganisms in STP	mg/L	9.10E-05
Comments		

9.2.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES2-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	2.87E-08
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	1.42E-08
Local PEC in grass land, averaged over 180 days	mg/kg dwt	1.34E-08
Comments		

9.2.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES2-E1*
Annual average local PEC in air (total)	mg/m^3	1.14E-05
Comments		

9.2.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.3. Exposure scenario 3: Distribution

9.3.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Distribution**
Sector of Use	SU3
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9, PROC15
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC1, 2, 3, 4, 5, 6, 7
Specific environmental release category	ESVOC 3, ESVOC SpERC 1.1b.v1
Processes, tasks, activities covered	Loading (including marine vessel/barge, reail/road car and IBC loading) and repacking (including drums and small packs) of substance, including its sampling, storage, unloading and associated laboratory activities.
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 100%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
Identifier*	***Contributing Scenarios***	***Process Categories***	***Risk Management Measures***
ES3-W1	General exposures (closed systems) [CS15]. ; Continuous process [CS54]. ; No sampling [CS57].	1	No other specific measures identified [EI20].
ES3-W2	General exposures (closed systems) [CS15]. ; Continuous process [CS54]. ; With sample collection [CS56].	2	No other specific measures identified [EI20].
ES3-W3	General exposures [CS1]. ; Use in contained batch processes [CS37]. ; With sample collection [CS56].	3	No other specific measures identified [EI20].
ES3-W4	General exposures (open systems) [CS16].	4	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES3-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES3-W6	Bulk transfers [CS14]. ; Dedicated facility [CS81]; (closed systems) [CS107]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES3-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]; (open systems) [CS108]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES3-W8	Drum/batch transfers [CS8]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES3-W9	Drum and small package filling [CS6]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES3-W10a	Equipment cleaning and maintenance [CS39].	8a	Avoid carrying out activities involving exposure for more than 1 hour [OC27].Wear suitable gloves tested to EN374 [PPE15].
ES3-W10b	Equipment cleaning and maintenance [CS39].	8a	Wear suitable gloves tested to EN374 [PPE15]. ; Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]
ES3-W11	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES3-W12	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

Section 2	Operational conditions and risk management measures
Section 2.2	**Control of environmental exposure**
Identifier	ES3-E1
Contributing scenario	Distrbution
Environmental Release Category	ERC1, 2, 3, 4, 5, 6, 7
Specific ERC	ESVOC 3, ESVOC SpERC 1.1b.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	1045
Fraction of EU tonnage used in region	1
Fraction of main source to local environment	0.002
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	7
Frequency and duration of use	
Type of release	continuous
Emission days (days/year)	300
Site specific monitoring data results for surface water effluent	Not applicable
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	
Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations.
Conditions and measures related to external recovery of waste	

Other environmental control measures additional to above	

9.3.2. Exposure estimation

9.3.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	industrial
Concentration:	> 25 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

*Identifier**	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES3-W1	General exposures (closed systems) [CS15]. ; Continuous process [CS54]. ; No sampling [CS57].	1	No other specific measures identified [EI20].	0.06	n.a.	0.34	n.a.	n.a.
ES3-W2	General exposures (closed systems) [CS15]. ; Continuous process [CS54]. ; With sample collection [CS56].	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES3-W3	General exposures [CS1]. ; Use in contained batch processes [CS37]. ; With sample collection [CS56].	3	No other specific measures identified [EI20].	19.03	n.a.	0.34	n.a.	n.a.
ES3-W4	General exposures (open systems) [CS16].	4	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	1.37	n.a.	n.a.
ES3-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	0.34	n.a.	n.a.
ES3-W6	Bulk transfers [CS14]. ;	8b	Provide a good standard of	22.20	n.a.	1.37	n.a.	n.a.

	Dedicated facility [CS81]; (closed systems) [CS107]		general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].					
ES3-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]; (open systems) [CS108]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	1.37	n.a.	n.a.
ES3-W8	Drum/batch transfers [CS8]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	1.37	n.a.	n.a.
ES3-W9	Drum and small package filling [CS6]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	1.37	n.a.	n.a.
ES3-W10a	Equipment cleaning and maintenance [CS39].	8a	Avoid carrying out activities involving exposure for more than 1 hour [OC27].Wear suitable gloves tested to EN374 [PPE15].	12.68	n.a.	2.74	n.a.	n.a.
ES3-W10b	Equipment cleaning and maintenance [CS39].	8a	Wear suitable gloves tested to EN374 [PPE15]. ; Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]	6.34	n.a.	2.74	n.a.	n.a.

ES3-W11	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES3-W12	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]	22.20	n.a.	0.34	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

9.3.2.2. Consumer exposure

Not applicable.

9.3.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.3.2.4. Environmental exposure

Identifier	*ES3-E1*
Narrative	Release fraction were estimated with ESVOC SpERC 1.1b.v1
Release fraction to air from process	1.00E-04
Release fraction to wastewater from process	1.00E-05
Release fraction to soil from process (regional only)	1.00E-05
Local release to air (kg/d)	0.00E+00
Local release to sewage (kg/d)	7.00E-05
Local release to soil (kg/d)	0
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	Not applicable
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	414350
Scaling	
The downstream user can check the compliance of his site by comparing site specific data with defaults used in the exposure assessment. The site specific quotient should be inferior or equal to the spERC quotient.	Not applicable as the exposure is generic and applies to the largest manufacturing capacity

$$\frac{m_{Safe} * (1 - E_{ER}) F^*_{release}}{DF} \geq \frac{m_{site} * (1 - E_{ER,site}) F^*_{release,site}}{DF_{site}}$$

m_{safe} Susbstance use rate in scenario (kg/d)

$E_{ER,spERC}$: Efficacy of RMM in scenario (-)
$F_{release,spERC}$: Initial release fraction in scenario (-)
DF: dilution factor of STP effluent in river

m_{site}: Susbstance use rate at site (kg/d)
$E_{ER,site}$: Efficacy of RMM at site (-)
$F_{release,site}$: Initial release fraction at site (-)
DF_{site}: dilution factor of STP effluent in river (-)

9.3.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES3-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	3.92E-06
Annual average local PEC in surface water (dissolved)	mg/L	1.68E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	1.66E-06
Local PEC in sea water during emission episode	mg/L	6.31E-06
Annual average local PEC in sea water (dissolved)	mg/L	1.44E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	1.42E-07
PEC for microorganisms in STP	mg/L	5.41E-07
Comments		

9.3.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES3-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	1.07E-09
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	8.63E-10
Local PEC in grass land, averaged over 180 days	mg/kg dwt	8.62E-10
Comments		

9.3.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES3-E1*
Annual average local PEC in air (total)	mg/m^3	1.75E-05
Comments		

9.3.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.4. Exposure scenario 4: Formulation and (re)packing of substances and mixtures

9.4.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Formulation and (re)packing of substances and mixtures**
Sector of Use	SU3
Process Category	PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC15
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC2
Specific environmental release category	ESVOC 3, ESVOC SpERC 1.1b.v1
Processes, tasks, activities covered	Formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, tabletting, compression, pelletisation, extrusion, large and small scale packing, sampling, maintenance and associated laboratory activities.
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 100%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
Identifier*	***Contributing Scenarios***	***Process Categories***	***Risk Management Measures***
ES4-W1	General exposures [CS1]. ; Continuous process [CS54]. ; No sampling [CS57]. ; (closed systems) [CS107]	1	No other specific measures identified [EI20].
ES4-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES4-W3	General exposures [CS1]. ; Use in contained batch processes [CS37]. ; With sample collection [CS56].	3	No other specific measures identified [EI20].
ES4-W4	General exposures (open systems) [CS16].	4	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES4-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES4-W6	Bulk transfers [CS14]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES4-W7	Mixing operations (open systems) [CS30].	5	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES4-W8	Transfer from/pouring from containers [CS22]. ; Manual [CS34].	8a	Avoid carrying out activities involving exposure for more than 1 hour [OC27].
ES4-W9	Drum/batch transfers [CS8]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES4-W10	Production or preparation or articles by tabletting, compression, extrusion or pelletisation [CS100]	14	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69].
ES4-W11	Drum and small package filling [CS6]. ; Dedicated facility [CS81]	9	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].
ES4-W12a	Equipment cleaning and maintenance [CS39].	8a	Avoid carrying out activities involving exposure for more than 1 hour [OC27].Wear suitable gloves tested to EN374 [PPE15].
ES4-W12b	Equipment cleaning and maintenance [CS39].	8a	Wear suitable gloves tested to EN374 [PPE15]. ; Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]
ES4-W13	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].
ES4-W14	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

Section 2	Operational conditions and risk management measures
Section 2.2	**Control of environmental exposure**
Identifier	ES4-E1
Contributing scenario	Formulation
Environmental Release Category	ERC2
Specific ERC	ESVOC 4, ESVOC SpERC 2.2.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	1045
Fraction of EU tonnage used in region	1
Fraction of main source to local environment	1
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	3500
Frequency and duration of use	
Type of release	Continuous
Emission days (days/year)	300
Site specific monitoring data results for surface water effluent	
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	Not applicable
Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations
Conditions and measures related to external recovery of waste	Storage of finished products in closed containers (e.g., bulk tanks,, drums, cans). Incinerate, absorb, or adsorb vapours stripped from solution whenever necessary.

Other environmental control measures additional to above	Vapour recovery units should be used when necessary.

9.4.2. Exposure estimation

9.4.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	industrial
Concentration:	> 25 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

Identifier	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES4-W1	General exposures [CS1]. ; Continuous process [CS54]. ; No sampling [CS57]. ; (closed systems) [CS107]	1	No other specific measures identified [EI20].	0.06	n.a.	0.34	n.a.	n.a.
ES4-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES4-W3	General exposures [CS1]. ; Use in contained batch processes [CS37]. ; With sample collection [CS56].	3	No other specific measures identified [EI20].	19.03	n.a.	0.34	n.a.	n.a.
ES4-W4	General exposures (open systems) [CS16].	4	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374	22.20	n.a.	1.37	n.a.	n.a.

			[PPE15].					
ES4-W5	Process sampling [CS2]. ; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	0.34	n.a.	n.a.
ES4-W6	Bulk transfers [CS14]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	1.37	n.a.	n.a.
ES4-W7	Mixing operations (open systems) [CS30].	5	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	2.74	n.a.	n.a.
ES4-W8	Transfer from/pouring from containers [CS22]. ; Manual [CS34].	8a	Avoid carrying out activities involving exposure for more than 1 hour [OC27].	12.68	n.a.	13.71	n.a.	n.a.
ES4-W9	Drum/batch transfers [CS8]. ; Dedicated facility [CS81]	8b	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374	22.20	n.a.	1.37	n.a.	n.a.

			[PPE15].					
ES4-W10	Production or preparation or articles by tabletting, compression, extrusion or pelletisation [CS100]	14	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69].	22.20	n.a.	3.43	n.a.	n.a.
ES4-W11	Drum and small package filling [CS6]. ; Dedicated facility [CS81]	9	Provide a good standard of general ventilation (not less than 3-5 air changes per hour) [E11]; or Ensure operation is undertaken outdoors [E69]. Wear suitable gloves tested to EN374 [PPE15].	22.20	n.a.	1.37	n.a.	n.a.
ES4-W12a	Equipment cleaning and maintenance [CS39].	8a	Avoid carrying out activities involving exposure for more than 1 hour [OC27].Wear suitable gloves tested to EN374 [PPE15].	12.68	n.a.	2.74	n.a.	n.a.
ES4-W12b	Equipment cleaning and maintenance [CS39].	8a	Wear suitable gloves tested to EN374 [PPE15]. ; Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]	6.34	n.a.	2.74	n.a.	n.a.
ES4-W13	Bulk product storage [CS85]; (closed systems) [CS107]	2	No other specific measures identified [EI20].	6.34	n.a.	1.37	n.a.	n.a.
ES4-W14	Laboratory activities [CS36].	15	Provide a good standard of general ventilation (not less than	22.20	n.a.	0.34	n.a.	n.a.

			3-5 air changes per hour) [E11]					

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

9.4.2.2. Consumer exposure

Not applicable.

9.4.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.4.2.4. Environmental exposure

Identifier	*ES4-E1*
Narrative	Release fraction were estimated with ESVOC 4, ESVOC 5, ESVOC SpERC 2.2.v1
Release fraction to air from process	0.025
Release fraction to wastewater from process	2.00E-04
Release fraction to soil from process (regional only)	1.00E-04
Local release to air (kg/d)	8.71E+01
Local release to sewage (kg/d)	0.70
Local release to soil (kg/d)	0.35
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	274300
Scaling	
The downstream user can check the compliance of his site by comparing site specific data with defaults used in the exposure assessment. The site specific quotient should be inferior or equal to the spERC quotient.	Not applicable as the exposure is generic and applies to the largest manufacturing capacity

$$\frac{m_{Safe} * (1 - E_{ER}) F^*_{release}}{DF} \geq \frac{m_{site} * (1 - E_{ER,site}) F^*_{release,site}}{DF_{site}}$$

m_{safe} Susbstance use rate in scenario (kg/d)
$E_{ER,spERC}$: Efficacy of RMM in scenario (-)
$F_{release,,spERC}$: Initial release fraction in scenario (-)
DF: dilution factor of STP effluent in river

m_{site}: Susbstance use rate at site (kg/d)
$E_{ER,site}$: Efficacy of RMM at site (-)

$F_{release,site}$: Initial release fraction at site (-)
DF_{site}: dilution factor of STP effluent in river (-)

9.4.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES4-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	0.00127
Annual average local PEC in surface water (dissolved)	mg/L	0.00104
Local PEC in fresh water sediment during emission episode	mg/kg dwt	0.00477
Local PEC in sea water during emission episode	mg/L	0.00013
Annual average local PEC in sea water (dissolved)	mg/L	0.00010
Local PEC in marine sediment during emission episode	mg/kg dwt	0.00048
PEC for microorganisms in STP	mg/L	0.01268
Comments		

9.4.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES4-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	2.80E-05
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	2.59E-05
Local PEC in grass land, averaged over 180 days	mg/kg dwt	2.92E-05
Comments		

9.4.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES4-E1*
Annual average local PEC in air (total)	mg/m^3	0.0199
Comments		

9.4.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.5. Exposure scenario 5: Industrial use in coatings (water based)

9.5.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Industrial use in coatings (water based)**
Sector of Use	SU3
Process Category	PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC4
Specific environmental release category	- ESVOC 5, ESVOC SpERC 4.3b.v1
Processes, tasks, activities covered	Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, spreader, dip, flow, fluidised bed on production lines and film formation) and equipment cleaning, maintenance and associated laboratory activities.
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 30%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
*Identifier**	*Contributing Scenarios*	*Process Categories*	*Risk Management Measures*
ES5-W1	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].
ES5-W2	General exposures (closed systems) [CS15]. ; With sample collection [CS56].	2	No other specific measures identified [EI20].
ES5-W3	Film formation - force drying (50 - 100°C). Stoving (>100°C). UV/EB radiation curing [CS94].	2	No other specific measures identified [EI20].
ES5-W4	Mixing operations (closed systems) [CS29]. ; General exposures (closed systems) [CS15].	3	No other specific measures identified [EI20].
ES5-W5	Film formation - air drying [CS95].	4	No other specific measures identified [EI20].
ES5-W6	Preparation of material for application [CS96]. ; Mixing operations (open systems) [CS30].	5	No other specific measures identified [EI20].
ES5-W7	Spraying (automatic/robotic) [CS97].	7	No other specific measures identified [EI20].
ES5-W8	Spraying [CS10]. ; Manual [CS34].	7	Wear suitable gloves tested to EN374 [PPE15]. ; Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]
ES5-W9	Material transfers [CS3]. ; Non-dedicated facility [CS82]	8a	Wear suitable gloves tested to EN374 [PPE15].
ES5-W10	Material transfers [CS3]. ; Dedicated facility [CS81]	8b	No other specific measures identified [EI20].
ES5-W11	Material transfers [CS3]. ; Drum/batch transfers [CS8]. ; Transfer from/pouring from containers [CS22]. ; Dedicated facility [CS81]	9	No other specific measures identified [EI20].
ES5-W12	Roller, spreader, flow application [CS98].	10	Wear suitable gloves tested to EN374 [PPE15].
ES5-W13	Dipping, immersion and pouring [CS4].	13	Wear suitable gloves tested to EN374 [PPE15].
ES5-W14	Laboratory activities [CS36].	15	No other specific measures identified [EI20].

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

Section 2	Operational conditions and risk management measures
Section 2.2	**Control of environmental exposure**
Identifier	ES5-E1
Contributing scenario	Industrial use in coatings
Environmental Release Category	ERC4
Specific ERC	ESVOC 5, ESVOC SpERC 4.3b.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	313
Fraction of EU tonnage used in region	1
Fraction of main source to local environment	1
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	1043
Frequency and duration of use	
Type of release	Continuous
Emission days (days/year)	300
Site specific monitoring data results for surface water effluent	Not applicable
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	70
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	Not applicable
Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations.
Conditions and measures related to external recovery of waste	Storage of finished products in closed containers (e.g., bulk tanks,, drums, cans). Incinerate, absorb, or adsorb vapours stripped from solution whenever necessary.

Other environmental control measures additional to above	Vapour recovery units should be used when necessary.

9.5.2. Exposure estimation

9.5.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	industrial
Concentration:	> 25 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

Identifier	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES5-W1	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].	0.02	n.a.	0.34	n.a.	n.a.
ES5-W2	General exposures (closed systems) [CS15]. ; With sample collection [CS56].	2	No other specific measures identified [EI20].	1.90	n.a.	1.37	n.a.	n.a.
ES5-W3	Film formation - force drying (50 - 100°C). Stoving (>100°C). UV/EB radiation curing [CS94].	2	No other specific measures identified [EI20].	19.03	n.a.	1.37	n.a.	n.a.
ES5-W4	Mixing operations (closed systems) [CS29]. ; General exposures (closed systems) [CS15].	3	No other specific measures identified [EI20].	5.71	n.a.	0.34	n.a.	n.a.
ES5-W5	Film formation - air drying [CS95].	4	No other specific measures identified [EI20].	9.51	n.a.	6.86	n.a.	n.a.
ES5-W6	Preparation of material for application [CS96]. ; Mixing operations (open systems) [CS30].	5	No other specific measures identified [EI20].	9.51	n.a.	13.71	n.a.	n.a.
ES5-W7	Spraying (automatic/robotic) [CS97].	7	No other specific measures identified [EI20].	9.51	n.a.	2.14	n.a.	n.a.
ES5-W8	Spraying [CS10]. ; Manual [CS34].	7	Wear suitable gloves tested to EN374 [PPE15]. ; Wear a respirator conforming to	19.03	n.a.	8.57	n.a.	n.a.

			EN140 with Type A filter or better. [PPE22]					
ES5-W9	Material transfers [CS3]. ; Non-dedicated facility [CS82]	8a	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES5-W10	Material transfers [CS3]. ; Dedicated facility [CS81]	8b	No other specific measures identified [EI20].	9.51	n.a.	6.86	n.a.	n.a.
ES5-W11	Material transfers [CS3]. ; Drum/batch transfers [CS8]. ; Transfer from/pouring from containers [CS22]. ; Dedicated facility [CS81]	9	No other specific measures identified [EI20].	9.51	n.a.	6.86	n.a.	n.a.
ES5-W12	Roller, spreader, flow application [CS98].	10	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	5.49	n.a.	n.a.
ES5-W13	Dipping, immersion and pouring [CS4].	13	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES5-W14	Laboratory activities [CS36].	15	No other specific measures identified [EI20].	9.51	n.a.	0.34	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

9.5.2.2. Consumer exposure

Not applicable.

9.5.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.5.2.4. Environmental exposure

Identifier	*ES5-E1*
Narrative	Release fraction were estimated with ESVOC 5, ESVOC SpERC 4.3b.v1
Release fraction to air from process	0.098
Release fraction to wastewater from process	7.00E-04
Release fraction to soil from process (regional only)	0.00E+00
Local release to air (kg/d)	1.02E+02
Local release to sewage (kg/d)	0.73
Local release to soil (kg/d)	0
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4

Total efficiency of removal from air emissions (%)	
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	78300
Scaling	
The downstream user can check the compliance of his site by comparing site specific data with defaults used in the exposure assessment. The site specific quotient should be inferior or equal to the spERC quotient.	Not applicable as the exposure is generic and applies to the largest manufacturing capacity

$$\frac{m_{Safe} * (1 - E_{ER}) F^*_{release}}{DF} \geq \frac{m_{site} * (1 - E_{ER,site}) F^*_{release,site}}{DF_{site}}$$

m_{safe} Susbstance use rate in scenario (kg/d)
$E_{ER,spERC}$: Efficacy of RMM in scenario (-)
$F_{release,spERC}$: Initial release fraction in scenario (-)
DF: dilution factor of STP effluent in river

m_{site}: Susbstance use rate at site (kg/d)
$E_{ER,site}$: Efficacy of RMM at site (-)
$F_{release,site}$: Initial release fraction at site (-)
DF_{site}: dilution factor of STP effluent in river (-)

9.5.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES5-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	1.33E-03
Annual average local PEC in surface water (dissolved)	mg/L	1.09E-03
Local PEC in fresh water sediment during emission episode	mg/kg dwt	5.00E-03
Local PEC in sea water during emission episode	mg/L	1.33E-04
Annual average local PEC in sea water (dissolved)	mg/L	1.09E-04
Local PEC in marine sediment during emission episode	mg/kg dwt	5.00E-04
PEC for microorganisms in STP	mg/L	1.33E-02
Comments		

9.5.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES5-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	3.25E-05
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	3.04E-05
Local PEC in grass land, averaged over 180 days	mg/kg dwt	3.42E-05
Comments		

9.5.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES5-E1*
Annual average local PEC in air (total)	mg/m^3	2.34E-02
Comments		

9.5.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.6. Exposure scenario 6: Professional use in coatings (solvent based)

9.6.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Professional use in coatings (solvent based)**
Sector of Use	SU22
Process Category	PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC10, PROC11, PROC13, PROC15, PROC19
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC8A, ERC8D
Specific environmental release category	ESVOC 6, ESVOC SpERC 8.3b.v1
Processes, tasks, activities covered	Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, brush, spreader by hand or similar methods, and film formation), and equipment cleaning, maintenance and associated laboratory activities.
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 30%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
Identifier*	***Contributing Scenarios***	***Process Categories***	***Risk Management Measures***
ES6-W1	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].
ES6-W2	Filling / preparation of equipment from drums or containers. [CS45].	2	No other specific measures identified [EI20].
ES6-W3	General exposures (closed systems) [CS15]. ; Use in contained systems [CS38].	2	No other specific measures identified [EI20].
ES6-W4	Preparation of material for application [CS96]	3	No other specific measures identified [EI20].
ES6-W5	Film formation - air drying [CS95]. ; Outdoor [OC9]	4	No other specific measures identified [EI20].
ES6-W6	Film formation - air drying [CS95]; Indoor [OC8]	4	No other specific measures identified [EI20].
ES6-W7	Preparation of material for application [CS96]; Indoor [OC8]	5	Wear suitable gloves tested to EN374 [PPE15].
ES6-W8	Preparation of material for application [CS96]; Outdoor [OC9]	5	Wear suitable gloves tested to EN374 [PPE15].
ES6-W9	Material transfers [CS3]. ; Drum/batch transfers [CS8]. ; Non-dedicated facility [CS82]	8a	Wear suitable gloves tested to EN374 [PPE15].
ES6-W10	Material transfers [CS3]. ; Dedicated facility [CS81]; Drum/batch transfers [CS8].	8b	No other specific measures identified [EI20].
ES6-W11	Roller, spreader, flow application [CS98]. ; Indoor [OC8]	10	Wear suitable gloves tested to EN374 [PPE15].
ES6-W12	Roller, spreader, flow application [CS98]; Outdoor [OC9]	10	Wear suitable gloves tested to EN374 [PPE15].
ES6-W13	Spraying [CS10]. ; Manual [CS34]. ; Outdoor [OC9]	11	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]; Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17].
ES6-W14	Spraying [CS10]. ; Manual [CS34]. ; Intdoor [OC8]	11	Carry out in a vented booth or extracted enclosure [E57]. Avoid carrying out activities involving exposure for more than 4 hours [OC28].
ES6-W15	Dipping, immersion and pouring [CS4]. ; Indoor [OC8]	13	Wear suitable gloves tested to EN374 [PPE15].

ES6-W16	Dipping, immersion and pouring [CS4]. ; Outdoor [OC9]	13	Wear suitable gloves tested to EN374 [PPE15].
ES6-W17	Laboratory activities [CS36].	15	No other specific measures identified [EI20].
ES6-W18	Hand application - fingerpaints, pastels, adhesives [CS72]; Indoor [OC8]	19	Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17].
ES6-W19	Hand application - fingerpaints, pastels, adhesives [CS72]; Outdoor [OC9]	19	Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17].

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

Section 2	**Operational conditions and risk management measures**
Section 2.2	**Control of environmental exposure**
Identifier	ES6-E1
Contributing scenario	Professional use in coatings
Environmental Release Category	ERC8A, ERC8D
Specific ERC	ESVOC 6, ESVOC SpERC 8.3b.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	16
Fraction of EU tonnage used in region	0.1
Fraction of main source to local environment	0.0005
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	0.002
Frequency and duration of use	
Type of release	Continuous
Emission days (days/year)	365
Site specific monitoring data results for surface water effluent	Not applicable
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	Not applicable

Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations.
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	

9.6.2. Exposure estimation

9.6.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	professional
Concentration:	< 30 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

Identifier	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES6-W1	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].	0.02	n.a.	0.34	n.a.	n.a.
ES6-W2	Filling / preparation of equipment from drums or containers. [CS45].	2	No other specific measures identified [EI20].	9.51	n.a.	1.37	n.a.	n.a.
ES6-W3	General exposures (closed systems) [CS15]. ; Use in contained systems [CS38].	2	No other specific measures identified [EI20].	9.51	n.a.	1.37	n.a.	n.a.
ES6-W4	Preparation of material for application [CS96]	3	No other specific measures identified [EI20].	5.71	n.a.	0.34	n.a.	n.a.
ES6-W5	Film formation - air drying [CS95]. ; Outdoor [OC9]	4	No other specific measures identified [EI20].	19.03	n.a.	6.86	n.a.	n.a.

ES6-W6	Film formation - air drying [CS95]; Indoor [OC8]	4	No other specific measures identified [EI20].	19.03	n.a.	6.86	n.a.	n.a.
ES6-W7	Preparation of material for application [CS96]; Indoor [OC8]	5	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES6-W8	Preparation of material for application [CS96]; Outdoor [OC9]	5	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES6-W9	Material transfers [CS3]. ; Drum/batch transfers [CS8]. ; Non-dedicated facility [CS82]	8a	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES6-W10	Material transfers [CS3]. ; Dedicated facility [CS81]; Drum/batch transfers [CS8].	8b	No other specific measures identified [EI20].	19.03	n.a.	6.86	n.a.	n.a.
ES6-W11	Roller, spreader, flow application [CS98]. ; Indoor [OC8]	10	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	5.49	n.a.	n.a.
ES6-W12	Roller, spreader, flow application [CS98]; Outdoor [OC9]	10	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	5.49	n.a.	n.a.
ES6-W13	Spraying [CS10]. ; Manual [CS34]. ; Outdoor [OC9]	11	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]; Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17].	19.03	n.a.	5.36	n.a.	n.a.
ES6-W14	Spraying [CS10]. ; Manual [CS34]. ; Intdoor [OC8]	11	Carry out in a vented booth or extracted enclosure [E57]. Avoid carrying out activities involving exposure for more than 4 hours [OC28].	22.83	n.a.	2.14	n.a.	n.a.
ES6-W15	Dipping, immersion and pouring [CS4]. ; Indoor [OC8]	13	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES6-W16	Dipping, immersion and pouring [CS4]. ; Outdoor [OC9]	13	Wear suitable gloves tested to EN374 [PPE15].	19.03	n.a.	2.74	n.a.	n.a.
ES6-W17	Laboratory activities [CS36].	15	No other specific measures identified [EI20].	19.03	n.a.	0.34	n.a.	n.a.

ES6-W18	Hand application - fingerpaints, pastels, adhesives [CS72]; Indoor [OC8]	19	Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17].	19.03	n.a.	7.07	n.a.	n.a.
ES6-W19	Hand application - fingerpaints, pastels, adhesives [CS72]; Outdoor [OC9]	19	Wear chemically resistant gloves (tested to EN374) in combination with specific activity training [PPE17].	19.03	n.a.	7.07	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

9.6.2.2. Consumer exposure

Not applicable.

9.6.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.6.2.4. Environmental exposure

Identifier	*ES6-E1*
Narrative	Release fraction were estimated with ESVOC 6, ESVOC SpERC 8.3b.v1
Release fraction to air from process	0.98
Release fraction to wastewater from process	1.00E-02
Release fraction to soil from process (regional only)	1.00E-02
Local release to air (kg/d)	0
Local release to sewage (kg/d)	2.19E-05
Local release to soil (kg/d)	0
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	

9.6.2.4.1 Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES6-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	1.59E-06
Annual average local PEC in surface water (dissolved)	mg/L	1.59E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	5.99E-06
Local PEC in sea water during emission episode	mg/L	1.35E-07
Annual average local PEC in sea water (dissolved)	mg/L	1.35E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	5.09E-07
PEC for microorganisms in STP	mg/L	3.99E-07
Comments		

9.6.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES6-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	6.87E-10
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	6.23E-10
Local PEC in grass land, averaged over 180 days	mg/kg dwt	6.14E-10
Comments		

9.6.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES6-E1*
Annual average local PEC in air (total)	mg/m^3	3.76E-06
Comments		

9.6.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.7. Exposure scenario 7: Consumer use in coatings (water based)

Exposure estimation was carried out for consumer uses of substance and its operational conditions as defined in the relevant exposure scenarios. The worst-case exposure situation was presented for a product with different types of application. Water borne paints and coatings may contain PPh. Long term exposures were estimated per ECHA (2010) guidance and tools because measured consumer exposures were not available.

9.6.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Consumer use in coatings (water based)**
Sector of Use	SU21
Process Category	n/a
Product Category	PC9a
Article Category	n/a
Environmental release Category	ERC8a, ERC8d
Specific environmental release category	ESVOC 7, ESVOC SpERC 8.3c.v1
Processes, tasks, activities covered	Covers the use in paints and coatings including exposures during use (including product preparation and mixing, application by brush or rolling, and equipment cleaning).
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of consumer exposure*
Product characteristics	
Physical form of product	Liquid
Vapour pressure	Moderate volatility (ECETOC Class B for Vapour pressure between 1 and 10 Pa)
Concentration of substance in product	Up to 5%
Operational conditions	
Product amounts used per event	Up to 2500 g (refined analysis).
Frequency and duration of use	One event per day for up to 4 hr; typically one event per year.
Other operational conditions affecting consumer exposure	Indoor application or outdoor application at ambient temperature. Worst case assumption used indoor application in room size of 20 m3 with open doors and open windows.
Human factors not influenced by risk management	Worse case assumption used indoor application.

*Identifier**	*Product or Article Categories*	*Product or Article (sub) Categories*	*Risk Management Measures*
ES7-C1	PC9a	Water borne paints and coatings	Avoid using at a product concentration greater than 5% [ConsRMM1]; For each use event, avoid using a product amount greater than 1880 grams [ConsRMM2]; Avoid using product more than one time per day [ConsRMM4]; for greater than 3 hours [ConsRMM14]; Avoid using in room with closed doors and closed windows [ConsRMM8].

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

Section 2	*Operational conditions and risk management measures*
Section 2.2	*Control of environmental exposure*
Identifier	ES7-E1
Contributing scenario	Consumer use in coatings
Environmental Release Category	ERC8d
Specific ERC	ESVOC 7, ESVOC SpERC 8.3c.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	17
Fraction of EU tonnage used in region	0.1
Fraction of main source to local environment	0.0005
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	0.0023
Frequency and duration of use	
Type of release	Continuous
Emission days (days/year)	365
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Conditions and measures related to municipal sewage treatment plant	
Estimated substance removal from wastewater via domestic sewage treatment (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Conditions and measures related to external treatment of waste for disposal	
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	Do not pour down the drain
	Dispose of waste cans and containers according to local regulations.
	Prevent exposure of soil using protecive covers

9.7.2. Exposure estimation

9.7.2.1. Workers exposure

Not applicable.

9.7.2.2. Consumer exposure

The consumer exposure estimates for the activities associated with the substance use have been assessed using a tiered approach beginning with the ECETOC TRA v2 and then applying the ConsExpo v4.1 model with its exposure scenario default database. For details of the exposure analysis, refer to Appendix Z

A water based paint product containing the maximum of 5% PPh was evaluated using the ConsExpo default scenario for water borne paint application. Brush and roller painting was selected as a worst case because the product use rate and exposure duration were greater and the room volume was smaller than for spray painting. The Tier 1 dermal exposure analysis assumed 100% relative dermal absorption of the liquid dose on the skin. The paint load on the skin was based on the ConsExpo default paint contact rate of 30 mg/min. The default scenario was modified to increase the exposure duration to 4 hours, the mass of paint to 2500 g, and the surface area to 20m2. A second modification was the PPh evaporation from the painted surface used the mass transfer coefficient from the Thibodeaux method based on McCready and Fontaine (2010). Oral exposure and use by children were not anticipated.

References

1. D. McCready and D. D. Fontaine. Refining ConsExpo Evaporation and Human Exposure Calculations for REACH. Human and Ecological Risk Assessment, Volume 16, Issue 4, pages 783 – 800. July 2010.
2. European Chemicals Agency (ECHA). Guidance for the Implementation of REACH, Chapter R.15: Consumer Exposure Estimation. April, 2010.

Identifier	*Product or Article Categories*	*Product or Article (sub) Categories*	*Risk Management Measures*	*Oral (mg/kg bw/day)*		*Dermal systemic (mg/kg bw/day)*		*Dermal local (mg/cm2/day)*		*Inhalation (mg/kg/day)*	
				Long Term	*Acute*	*Long term*	*Acute*	*Long term*	*Acute*	*Long term*	*Acute*
ES7-C1	PC9a	Water borne paints default analysis	Avoid using at a product concentration greater than 5%. Avoid using a product amount greater than 1250 g more than one time per day for greater than 2 hours. Avoid using in room with closed doors and closed windows.	n.a.	n.a.	2.77	n.a.	n.a.	n.a.	0.017	n.a.
ES7-C2	PC9a	Water borne paints modified analysis	Avoid using at a product concentration greater than 5%. Avoid using a product amount greater than 2500 g more than one time per day for greater than 4	n.a.	n.a.	6.0	n.a.	n.a.	n.a.	0.046	n.a.

			hours. Avoid using in room with closed doors and closed windows.								

9.7.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.7.2.4. Environmental exposure

Identifier	*ES7-E1*
Narrative	The exposure scenario is based on ESVOC 7, ESVOC SpERC 8.3c.v1
Release fraction to air	0.985
Release fraction to wastewater	0.01
Release fraction to soil (regional only)	0.005
Local release to air (kg/d)	0
Local release to sewage (kg/d)	2.33E-05
Local release to soil (kg/d)	0
Fraction remaining in water after STP treatement (Fwater)	
Removal in STP (fraction)	96.4

9.7.2.4.1. Predicted exposure concentrations in aquatic the STP and in the aquatic compartments (freshwater, seawater and sediments)

Local Concentration, Compartment: STP and aquatic	*unit*	ES7-E1
Local PEC in surface water during emission episode (dissolved)	mg/L	1.60E-06
Annual average local PEC in surface water (dissolved)	mg/L	1.60E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	6.00E-06
Local PEC in sea water during emission episode	mg/L	1.36E-07
Annual average local PEC in sea water (dissolved)	mg/L	1.36E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	5.10E-07
PEC for microorganisms in STP	mg/L	4.24E-07
Comments		

9.7.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	ES7-E1
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	6.92E-10
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	6.24E-10
Local PEC in grass land, averaged over 180 days	mg/kg dwt	6.15E-10
Comments		

9.7.2.4.3 Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	ES7-E1
Annual average local PEC in air (total)	mg/m^3	3.76E-06
Comments		

9.7.2.4.4 Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.8. Exposure scenario 8: Professional use in cleaning agents

9.8.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Professional use in cleaning agents**
Sector of Use	SU22
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC10, PROC13
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC8A, ERC8D
Specific environmental release category	ESVOC 9 ESVOC SpERC 8.4b.v1
Processes, tasks, activities covered	Covers the use as a component of cleaning products including pouring/unloading from drums or containers; and exposures during mixing/diluting in the preparatory phase and cleaning activities (including spraying, brushing, dipping, wiping automated and by hand).
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 10%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
*Identifier**	*Contributing Scenarios*	*Process Categories*	*Risk Management Measures*
ES8-W1	Filling / preparation of equipment from drums or containers. [CS45]. ; Dedicated facility [CS81]	8b	No other specific measures identified [EI20].
ES8-W2	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].
ES8-W3	Use in contained systems [CS38]. ; Automated process with (semi) closed systems [CS93]	2	No other specific measures identified [EI20].
ES8-W4	Use in contained systems [CS38]. ; Automated process with (semi) closed systems [CS93]; Drum/batch transfers [CS8].	3	No other specific measures identified [EI20].

ES8-W5	Semi Automated process. (e.g.: Semi automatic application of floor care and maintenance products) [CS76]	4	No other specific measures identified [EI20].
ES8-W6	Filling / preparation of equipment from drums or containers. [CS45]. ; Non-dedicated facility [CS82]; Outdoor [OC9]	8a	No other specific measures identified [EI20].
ES8-W7	Cleaning [CS47]. ; Surfaces [CS48]. ; Manual [CS34]. ; Dipping, immersion and pouring [CS4].	13	No other specific measures identified [EI20].
ES8-W8	Cleaning with low-pressure washers [CS42].	10	Wear suitable gloves tested to EN374 [PPE15].
ES8-W9	Cleaning [CS47]. ; Surfaces [CS48]. ; Manual [CS34]. ; Spraying [CS10].	10	Wear suitable gloves tested to EN374 [PPE15].
ES8-W10	Ad hoc manual application via trigger sprays, dipping, etc. [CS27]. ; Rolling, Brushing [CS51].	10	Wear suitable gloves tested to EN374 [PPE15].
ES8-W11	Ad hoc manual application via trigger sprays, dipping, etc. [CS27]. ; Rolling, Brushing [CS51].	10	Wear suitable gloves tested to EN374 [PPE15].
ES8-W12	Application of cleaning products in closed systems [CS101]	4	No other specific measures identified [EI20].
ES8-W13	Cleaning of medical devices [CS74]	4	No other specific measures identified [EI20].

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

Section 2	**Operational conditions and risk management measures**
Section 2.2	**Control of environmental exposure**
Identifier	ES8-E1
Contributing scenario	Professional use in cleaning agents
Environmental Release Category	ERC8d
Specific ERC	ESVOC 9 ESVOC SpERC 8.4b.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	110
Fraction of EU tonnage used in region	0.1
Fraction of main source to local environment	0.0005
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	0.0151
Frequency and duration of use	

Type of release	continuous
Emission days (days/year)	365
Site specific monitoring data results for surface water effluent	
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	70
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	Not applicable
Organizational measures to prevent/limit release from site	
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations.
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	

9.8.2. Exposure estimation

9.8.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	professional
Concentration:	< 10 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

Identifier *	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES8-W1	Filling / preparation of equipment from drums or containers. [CS45]. ; Dedicated facility [CS81]	8b	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.
ES8-W2	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].	0.01	n.a.	0.34	n.a.	n.a.
ES8-W3	Use in contained systems [CS38]. ; Automated process with (semi) closed systems [CS93]	2	No other specific measures identified [EI20].	3.17	n.a.	1.37	n.a.	n.a.
ES8-W4	Use in contained systems [CS38]. ; Automated process with (semi) closed systems [CS93]; Drum/batch transfers [CS8].	3	No other specific measures identified [EI20].	1.90	n.a.	0.34	n.a.	n.a.
ES8-W5	Semi Automated process. (e.g.: Semi automatic application of floor care and maintenance products) [CS76]	4	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.
ES8-W6	Filling / preparation of equipment from drums or containers. [CS45]. ; Non-dedicated facility [CS82]; Outdoor [OC9]	8a	No other specific measures identified [EI20].	15.85	n.a.	13.71	n.a.	n.a.
ES8-W7	Cleaning [CS47]. ; Surfaces [CS48]. ; Manual [CS34]. ; Dipping, immersion and pouring [CS4].	13	No other specific measures identified [EI20].	6.34	n.a.	13.71	n.a.	n.a.
ES8-W8	Cleaning with low-pressure washers [CS42].	10	Wear suitable gloves tested to EN374 [PPE15].	15.85	n.a.	5.49	n.a.	n.a.
ES8-W9	Cleaning [CS47]. ; Surfaces [CS48]. ; Manual [CS34]. ; Spraying [CS10].	10	Wear suitable gloves tested to EN374 [PPE15].	15.85	n.a.	5.49	n.a.	n.a.
ES8-W10	Ad hoc manual application via trigger sprays, dipping, etc. [CS27]. ; Rolling, Brushing [CS51].	10	Wear suitable gloves tested to EN374 [PPE15].	15.85	n.a.	5.49	n.a.	n.a.
ES8-W11	Ad hoc manual application via trigger sprays, dipping, etc. [CS27]. ; Rolling, Brushing [CS51].	10	Wear suitable gloves tested to EN374 [PPE15].	15.85	n.a.	5.49	n.a.	n.a.
ES8-W12	Application of cleaning products in closed systems [CS101]	4	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.
ES8-W13	Cleaning of medical devices [CS74]	4	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

9.8.2.2. Consumer exposure

Not applicable.

9.8.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.8.2.4. Environmental exposure

Identifier	*ES8-E1*
Narrative	Release fraction were estimated with ESVOC 9 ESVOC SpERC 8.4b.v1
Release fraction to air from process	2.00E-02
Release fraction to wastewater from process	1.00E-06
Release fraction to soil from process (regional only)	0
Local release to air (kg/d)	0
Local release to sewage (kg/d)	1.51E-08
Local release to soil (kg/d)	0
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	

9.8.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES8-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	1.55E-06
Annual average local PEC in surface water (dissolved)	mg/L	1.55E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	5.84E-06
Local PEC in sea water during emission episode	mg/L	1.31E-07
Annual average local PEC in sea water (dissolved)	mg/L	1.31E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	4.94E-07
PEC for microorganisms in STP	mg/L	2.74E-10
Comments		

9.8.2.4.1. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES8-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	6.05E-10
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	6.05E-10
Local PEC in grass land, averaged over 180 days	mg/kg dwt	6.05E-10
Comments		

9.8.2.4.2. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES8-E1*
Annual average local PEC in air (total)	mg/m^3	3.76E-06
Comments		

9.8.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.9. Exposure scenario 9: Consumer use in cleaning agents

Exposure estimation was carried out for consumer uses of substance and its operational conditions as defined in the relevant exposure scenarios. The worst-case exposure situation was presented for a product with different types of application. Consumer cleaning agents and detergents may contain PPh. Long term exposures were estimated per ECHA (2010) guidance and tools because measured consumer exposures were not available.

9.9.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Consumer use in cleaning agents**
Sector of Use	SU21
Process Category	n/a
Product Category	PC35
Article Category	n/a
Environmental release Category	ERC8A, 8D
Specific environmental release category	ESVOC SpERC 8.4c.v1
Processes, tasks, activities covered	Covers the use in cleaning agents and detergents including spraying, wiping, and mopping.
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of consumer exposure*
Product characteristics	
Physical form of product	Liquid
Vapour pressure	Moderate volatility (ECETOC Class B for Vapour pressure between 1 and 10 Pa)
Concentration of substance in product	Up to 5%
Operational conditions	
Product amounts used per event	Trigger spray surface cleaner up to 48 g. Floor cleaning up to 880 g.
Frequency and duration of use	Trigger sprays up 3 events per day for up to 3 hr. Floor cleaning up to 4 hour per day
Other operational conditions affecting consumer exposure	Use at ambient temperatures in room size of at least 15 m3 with typical household ventilation.
Human factors not influenced by risk management	Worse case assumption used indoor application.

Identifier *	*Product or Article Categories*	*Product or Article (sub) Categories*	*Risk Management Measures*
ES9-C1	PC35	Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) including spraying and wiping.	Avoid using a product concentration greater than 5% [ConsRMM1]. For each event, avoid using a product amount greater than 48 g [ConsRMM2]. Avoid using product longer than one hour per day [ConsRMM14].
ES9-C2	PC35	Floor cleaning liquid including mixing & loading and application.	Avoid using a product concentration greater than 5% [ConsRMM1]. For each event, avoid using a product amount greater than 880 g [ConsRMM2].]. Avoid using product longer than four hours per day [ConsRMM14].

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

Section 2	*Operational conditions and risk management measures*
Section 2.2	*Control of environmental exposure*
Identifier	ES9-E1
Contributing scenario	Consumer use in cleaning
Environmental Release Category	ERC8d
Specific ERC	ESVOC 10, ESVOC SpERC 8.4c.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	110
Fraction of EU tonnage used in region	0.1
Fraction of main source to local environment	0.0005
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	0.015
Frequency and duration of use	
Type of release	continuous
Emission days (days/year)	365
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Conditions and measures related to municipal sewage treatment plant	
Estimated substance removal from wastewater via domestic sewage treatment (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Conditions and measures related to external treatment of waste for disposal	
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	

9.9.2. Exposure estimation

9.9.2.1. Workers exposure

Not applicable.

9.9.2.2. Consumer exposure

The consumer exposure estimates for the activities associated with the substance use have been assessed using a tiered approach beginning with the ECETOC TRA v2 and then applying the ConsExpo v4.1 model with its exposure scenario default database. For details of the predicted exposures, refer to Appendix Z

The exposure scenarios evaluated a hard surface cleaner containing the maximum of 5% PPh. They were based on the ConsExpo default scenarios for two cases: spray application and wiping. The hard surface cleaner was selected as a worst case because of the potential for inhalation, dermal, and oral exposure and it can be used on a daily basis. The Tier 1 dermal exposure analyses assumed 100% relative dermal absorption of the liquid on the skin. The exposed area of 183 cm2 was equivalent to one side of an adult female hand and the female body weight was 60 kg. The Tier 2 inhalation analyses estimated exposure to the respirable aerosol from spraying a hard surface cleaner and the evaporation after wiping a surface with a hard surface cleaner. The PPh evaporation from the surface used the mass transfer coefficient from the Thibodeaux method based on McCready and Fontaine (2010). Oral exposure was based on ingestion of the non-respirable aerosol from spraying. A maximum of 3 events per day was evaluated to increase the product operational conditions.

The exposure scenarios evaluated a floor cleaner containing the maximum of 5% PPh. They were based on the ConsExpo default scenarios for two cases: mixing & loading and application. The Tier 1 dermal exposure analyses assumed 100% relative dermal absorption of the liquid on the skin. The Tier 2 inhalation analyses estimated exposure from evaporation after wiping the floor surface with a cleaner and the evaporation used the mass transfer coefficient from the Thibodeaux method based on McCready and Fontaine (2010). Oral exposure was based on ingestion of the non-respirable aerosol from spraying. Use by children was not anticipated.

Identifier	*Product or Article Categories*	*Product or Article (sub) Categories*	*Risk Management Measures*	*Oral (mg/kg bw/day)*		*Dermal systemic (mg/kg bw/day)*		*Dermal local (mg/cm2/day)*		*Inhalation (mg/kg/day)*	
				Long Term	*Acute*	*Long term*	*Acute*	*Long term*	*Acute*	*Long term*	*Acute*
ES9-C1	PC35	Trigger spray cleaner spraying and wiping.	Avoid using a product concentration greater than 5% [ConsRMM1]. For each event, avoid using a product amount greater than 48 g [ConsRMM2]. Avoid using product longer than one hour per day	0.001	n.a.	0.45	n.a.	n.a.	n.a.	0.002	n.a.
ES9-C2	PC35	Floor cleaning liquid including mixing & loading and	Avoid using a product concentration greater than 5% [ConsRMM1].	n.a.	n.a.	15.81	n.a.	n.a.	n.a.	0.02	n.a.

		application.	For each event, avoid using a product amount greater than 880 g [ConsRMM2].]. Avoid using product longer than four hours per day.								

9.9.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.9.2.4. Environmental exposure

Identifier	*ES9-E1*
Narrative	The exposure scenario is based on ESVOC SpERC 8.4c.v1
Release fraction to air	0.95
Release fraction to wastewater	0.025
Release fraction to soil (regional only)	0.025
Local release to air (kg/d)	0
Local release to sewage (kg/d)	3.77E-04
Local release to soil (kg/d)	0
Fraction remaining in water after STP treatement (Fwater)	
Removal in STP (fraction)	96.4

9.9.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	ES9-E1
Local PEC in surface water during emission episode (dissolved)	mg/L	2.24E-06
Annual average local PEC in surface water (dissolved)	mg/L	2.24E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	8.41E-06
Local PEC in sea water during emission episode	mg/L	2.00E-07
Annual average local PEC in sea water (dissolved)	mg/L	2.00E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	7.51E-07
PEC for microorganisms in STP	mg/L	6.86E-06
Comments		

9.9.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	ES9-E1
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	2.01E-09
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	9.13E-10
Local PEC in grass land, averaged over 180 days	mg/kg dwt	7.57E-10
Comments		

9.9.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	ES9-E1
Annual average local PEC in air (total)	mg/m^3	3.80E-06
Comments		

9.9.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.10. Exposure scenario 10: Professional use in metal working fluids/rolling oils

9.10.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Professional use in metal working fluids/rolling oils**
Sector of Use	SU22
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC10, PROC11, PROC13, PROC17
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC8A, ERC8D
Specific environmental release category	ESVOC SpERC 8.11a.v1
Processes, tasks, activities covered	Use as an agrochemical excipient for application by manual or machine spraying, smokes and fogging; including equipment clean-downs and disposal.
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	Up to 10%
Operational conditions	
Amounts used	Not relevant for this scenario
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated) [OC1]
Human factors not influenced by risk management	None identified for this scenario.
Other Operational Conditions affecting worker exposure	Assumes use at not > 20oC above ambient [OC6] Assumes a good basic standard of occupational hygiene is implemented [G1].

Risk Management Measures		*For detailed information on this Exposure Scenario, refer to appendix X.*	
Identifier*	***Contributing Scenarios***	***Process Categories***	***Risk Management Measures***
ES10-W1	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].
ES10-W2	General exposures (closed systems) [CS15]. ; Batch process [CS55].	3	No other specific measures identified [EI20].
ES10-W3	General exposures (open systems) [CS16]. ; Batch process [CS55].	4	No other specific measures identified [EI20].
ES10-W4	General exposures (closed systems) [CS15]. ; With sample collection [CS56].	2	No other specific measures identified [EI20].
ES10-W5	Material transfers [CS3]. ; Dedicated facility [CS81]	8b	No other specific measures identified [EI20].
ES10-W6	Filling / preparation of equipment from drums or containers. [CS45].	8b	No other specific measures identified [EI20].
ES10-W7	Filling / preparation of equipment from drums or containers. [CS45].	9	No other specific measures identified [EI20].
ES10-W8	Process sampling [CS2].	3	No other specific measures identified [EI20].
ES10-W9	Metal machining operations [CS79]	17	Provide extract ventilation to points where emissions occur [E54].
ES10-W10	Metal machining operations [CS79]; with potential for aerosol generation [CS138]	17	Provide extract ventilation to points where emissions occur [E54].
ES10-W11	Treatment by dipping and pouring [CS35].	13	No other specific measures identified [EI20].
ES10-W12	Spraying [CS10].	11	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]; Wear suitable gloves tested to EN374 [PPE15].
ES10-W13	Roller, spreader, flow application [CS98].	10	Wear suitable gloves tested to EN374 [PPE15].
ES10-W14	Equipment cleaning and maintenance [CS39].	8a	No other specific measures identified [EI20].
ES10-W15	Storage [CS67]; (closed systems) [CS107]	2	No other specific measures identified [EI20].

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES

Section 2	Operational conditions and risk management measures
Section 2.2	**Control of environmental exposure**
Identifier	ES10-E1
Contributing scenario	Professional use in metal working fluids
Environmental Release Category	ERC8d
Specific ERC	ESVOC 19, ESVOC SpERC 8.11a.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	211
Fraction of EU tonnage used in region	0.1
Fraction of main source to local environment	0.0005
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	0.029
Frequency and duration of use	
Type of release	continuous
Emission days (days/year)	365
Site specific monitoring data results for surface water effluent	
Location of sample	
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Technical conditions and measures at process level (source) to prevent release	Not applicable
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	Not applicable
Treat air emissions to provide a typical removal efficiency of (%)	
ERMM1: Typical onsite wastewater treatment technology provides degradation efficiency of (%)	
Organizational measures to prevent/limit release from site	Site should have a spill plan to ensure that adequate safeguards are in place to minimize the impact of episodic releases.
Conditions and measures related to municipal sewage treatment plant	
ERMM2: Typical municipal wastewater treatment technology provides degradation efficiency of (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Treat wastewater (prior to discharge to receiving water) to provide the required removal efficiency of (%) ETotal,RMM = 1 – ((1 – ERMM, 1) x (1 – ERMM,2))	STP4: Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%): 96.4
Conditions and measures related to external treatment of waste for disposal	Dispose of waste solvent and used containers according to local regulations
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	

9.10.2. Exposure estimation

9.10.2.1. Workers exposure

The worker exposure estimates for the activities associated with this use of PPh have been assessed using ECETOC TRA v2, unless stated differently (see appendix X).

Assessment parameter default values:

Fugacity:	low
Type of Use;	professional
Concentration:	< 10 %
Local Exhaust Ventilation:	none
Duration of Exposure:	> 4 hours/day
Respiratory Protection Equipment:	none

The ECETOC TRA v2 estimates shown are representative for activities lasting up to 8 hours.

*Identifier**	*Contributing scenarios*	*PROC*	*Risk Management Measures*	*Inhalatory exposure (mg/m3)*		*Dermal exposure (mg/kg/day)*		*Dermal exposure (mg/cm2)*
				Long term	*Acute*	*Long term*	*Acute systemic*	*Acute local*
ES10-W1	General exposures (closed systems) [CS15].	1	No other specific measures identified [EI20].	0.01	n.a.	0.34	n.a.	n.a.
ES10-W2	General exposures (closed systems) [CS15]. ; Batch process [CS55].	3	No other specific measures identified [EI20].	1.90	n.a.	0.34	n.a.	n.a.
ES10-W3	General exposures (open systems) [CS16]. ; Batch process [CS55].	4	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.
ES10-W4	General exposures (closed systems) [CS15]. ; With sample collection [CS56].	2	No other specific measures identified [EI20].	3.17	n.a.	1.37	n.a.	n.a.
ES10-W5	Material transfers [CS3]. ; Dedicated facility [CS81]	8b	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.
ES10-W6	Filling / preparation of equipment from drums or containers. [CS45].	8b	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.
ES10-W7	Filling / preparation of equipment from drums or containers.	9	No other specific measures identified [EI20].	6.34	n.a.	6.86	n.a.	n.a.

	[CS45].							
ES10-W8	Process sampling [CS2].	3	No other specific measures identified [EI20].	1.90	n.a.	0.34	n.a.	n.a.
ES10-W9	Metal machining operations [CS79]	17	Provide extract ventilation to points where emissions occur [E54].	6.34	n.a.	1.37	n.a.	n.a.
ES10-W10	Metal machining operations [CS79]; with potential for aerosol generation [CS138]	17	Provide extract ventilation to points where emissions occur [E54].	1.00	n.a.	n.a.	n.a.	n.a.
ES10-W11	Treatment by dipping and pouring [CS35].	13	No other specific measures identified [EI20].	6.34	n.a.	13.71	n.a.	n.a.
ES10-W12	Spraying [CS10].	11	Wear a respirator conforming to EN140 with Type A filter or better. [PPE22]; Wear suitable gloves tested to EN374 [PPE15].	6.34	n.a.	21.43	n.a.	n.a.
ES10-W13	Roller, spreader, flow application [CS98].	10	Wear suitable gloves tested to EN374 [PPE15].	15.85	n.a.	5.49	n.a.	n.a.
ES10-W14	Equipment cleaning and maintenance [CS39].	8a	No other specific measures identified [EI20].	15.85	n.a.	13.71	n.a.	n.a.
ES10-W15	Storage [CS67]; (closed systems) [CS107]	2	No other specific measures identified [EI20].	3.17	n.a.	1.37	n.a.	n.a.

*Identifier: each contributing scenario of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this contributing scenario of the ES.

9.10.2.2. Consumer exposure

Not applicable.

9.10.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.10.2.4. Environmental exposure

Identifier	*ES10-E1*
Narrative	Release fraction were estimated with ESVOC 19, ESVOC SpERC 8.11a.v1
Release fraction to air from process	4.00E-01
Release fraction to wastewater from process	5.00E-02
Release fraction to soil from process (regional only)	5.00E-02
Local release to air (kg/d)	0
Local release to sewage (kg/d)	1.40E-03
Local release to soil (kg/d)	0
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%)	96.4
Total efficiency of removal from air emissions (%)	
The maximum allowable site tonnage (M_{Safe}) based on removal from domestic sewage treatment (kg/d)	692
Scaling	
The downstream user can check the compliance of his site by comparing site specific data with defaults used in the exposure assessment. The site specific quotient should be inferior or equal to the spERC quotient.	Not applicable as the exposure is generic and applies to the largest manufacturing capacity

$$\frac{m_{Safe} * (1 - E_{ER}) F_{release}^{*}}{DF} \geq \frac{m_{site} * (1 - E_{ER,site}) F_{release,site}^{*}}{DF_{site}}$$

m_{safe} Susbstance use rate in scenario (kg/d)
$E_{ER,spERC}$: Efficacy of RMM in scenario (-)
$F_{release,spERC}$: Initial release fraction in scenario (-)
DF: dilution factor of STP effluent in river

m_{site}: Susbstance use rate at site (kg/d)
$E_{ER,site}$: Efficacy of RMM at site (-)
$F_{release,site}$: Initial release fraction at site (-)
DF_{site}: dilution factor of STP effluent in river (-)

9.10.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	*ES10-E1*
Local PEC in surface water during emission episode (dissolved)	mg/L	4.18E-06
Annual average local PEC in surface water (dissolved)	mg/L	4.18E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	1.57E-05
Local PEC in sea water during emission episode	mg/L	3.94E-07
Annual average local PEC in sea water (dissolved)	mg/L	3.94E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	1.48E-06
PEC for microorganisms in STP	mg/L	2.63E-05
Comments		

9.10.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	*ES10-E1*
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	5.99E-09
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	1.78E-09
Local PEC in grass land, averaged over 180 days	mg/kg dwt	1.18E-09
Comments		

9.10.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	*ES10-E1*
Annual average local PEC in air (total)	mg/m^3	4.02E-06
Comments		

9.10.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.11. Exposure scenario 11: Use in cosmetics (environment)

The risk to human health for ingredients of cosmetic products is assessed within the cosmetic directive framework.

9.11.1. Exposure scenario

Section 1	*Exposure Scenario Title*
Title	**Use in cosmetics (environment)**
Sector of Use	SU21
Process Category	n/a
Product Category	n/a
Article Category	n/a
Environmental release Category	ERC8A
Specific environmental release category	ESVOC 37, ESVOC SpERC 8.16.v1
Processes, tasks, activities covered	Covers the use in cosmetics (e.g. fingernails polish, polish remover, etc.)
Section 2	*Operational conditions and risk management measures*
Section 2.1	*Control of worker exposure*
Product characteristics	
Physical form of product	Liquid
Volatility	Low volatility
Concentration of substance in product	n/a
Operational conditions	
Amounts used	n/a
Frequency and duration of use	n/a
Human factors not influenced by risk management	n/a
Other Operational Conditions affecting worker exposure	n/a

Section 2	*Operational conditions and risk management measures*
Section 2.2	*Control of environmental exposure*
Identifier	ES11-E1
Contributing scenario	Consumer use in personal care
Environmental Release Category	ERC8d
Specific ERC	ESVOC 37, ESVOC SpERC 8.16.v1
Assessment scenario	
Operational Conditions	
Amounts used	
Amounts used in the EU (tonnes/year)	50
Fraction of EU tonnage used in region	0.1
Fraction of main source to local environment	0.0005
Fraction of substance in end-use products	
Daily site tonnage Msperc (kg/day)	0.0068
Frequency and duration of use	
Type of release	continuous
Emission days (days/year)	365
Environmental factors not influenced by risk management	
Local freshwater dilution factor	10 (default)
Local marine water dilution factor	100 (default)
Other given operational conditions affecting environmental exposure	
Risk Management Measures	
Conditions and measures related to municipal sewage treatment plant	
Estimated substance removal from wastewater via domestic sewage treatment (%)	STP: 3 Estimated substance removal from wastewater via domestic sewage treatment (%): 96.4 (default from Simple treat model)
Conditions and measures related to external treatment of waste for disposal	
Conditions and measures related to external recovery of waste	
Other environmental control measures additional to above	

9.11.2. Exposure estimation

9.11.2.1. Workers exposure

Not applicable.

9.10.2.2. Consumer exposure

Not applicable.

9.11.2.3. Indirect exposure of humans via the environment (oral)

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

9.11.2.4. Environmental exposure

Identifier	*ES11-E1*
Narrative	The exposure scenario is based on ESVOC 37, ESVOC SpERC 8.16.v1
Release fraction to air	0.95
Release fraction to wastewater	0.025
Release fraction to soil (regional only)	0.025
Local release to air (kg/d)	0
Local release to sewage (kg/d)	1.71E-04
Local release to soil (kg/d)	0
Fraction remaining in water after STP treatement (Fwater)	
Removal in STP (fraction)	96.4

9.11.2.4.1. Predicted exposure concentrations in aquatic the STP and in aquatic compartments (freshwater, seawater and sediment)

Local Concentration, Compartment: STP and aquatic	*unit*	ES11-E1
Local PEC in surface water during emission episode (dissolved)	mg/L	1.866E-06
Annual average local PEC in surface water (dissolved)	mg/L	1.866E-06
Local PEC in fresh water sediment during emission episode	mg/kg dwt	7.008E-06
Local PEC in sea water during emission episode	mg/L	1.626E-07
Annual average local PEC in sea water (dissolved)	mg/L	1.626E-07
Local PEC in marine sediment during emission episode	mg/kg dwt	6.107E-07
PEC for microorganisms in STP	mg/L	3.117E-06
Comments		

9.11.2.4.2. Predicted exposure concentration in soils

Local Concentration, Compartment: soil	*unit*	ES11-E1
Local PEC in agricultural soil, averaged over 30 days	mg/kg dwt	1.243E-09
Local PEC agricultural soil, averaged over 180 days	mg/kg dwt	7.447E-10
Local PEC in grass land, averaged over 180 days	mg/kg dwt	6.735E-10
Comments		

9.11.2.4.3. Predicted exposure concentration in the atmospheric compartment

Local Concentration, Compartment: air	*unit*	ES11-E1
Annual average local PEC in air (total)	mg/m^3	3.787E-06
Comments		

9.11.2.4.4. Predicted exposure concentration in food for secondary poisoning

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.

9.12 Regional exposure concentrations

Regional concentrations	*unit*	*value*
Regional PEC in surface water (total)	mg/L	1.55E-06
Regional PEC in sea water (total)	mg/L	1.31E-07
Regional PEC in air (total)	kg/m^3	3.76E-06
Regional PEC in agricultural soil (total)	mg/kg dwt	2.18E-07
Regional PEC in natural soil (total)	mg/kg dwt	6.06E-10
Regional PEC in industrial soil (total)	mg/kg dwt	6.06E-10
Regional PEC in sediment (total)	mg/kg dwt	4.97E-06
Regional PEC in sea water sediment (total)	mg/kg dwt	4.27E-07
Comments		

9.13. Qualitative assessment of risks from eye irritation

PPh is classified as an eye irritant (R36/H319).

This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation include eye irritation.

This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.

For eye irritation a qualitative risk characterisation has been conducted. Handling and storage risk management measures that are generally identified for eye irritation risks are outlined in the table in chapter 10.13.

A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye irritation are considered to be controlled. These measures should be communicated via the safety data sheet by use of the following phrase:

- [PPE26]: Use suitable eye protection.
- [E73]: Avoid direct eye contact with product, also via contamination on hands.

10. RISK CHARACTERISATION

The risk characterisation of Propylene Glycol Phenyl Ether has been conducted based on the PNECs and DNELs in the following tables.

Table 10.1 PNECs

Compartments	*PNEC*	
STP	10	mg L^{-1}
Freshwater	0.100	mg L^{-1}
Freshwater sediment	0.380	mg kg_{dwt}^{-1}
Marine water	0.010	mg L^{-1}
Marine water sediment	0.038	mg kg_{dwt}^{-1}
Soil	0.020	mg kg_{dwt}^{-1}

Table 10.2 DN(M)ELs for workers

Acute – systemic effects		*Acute – local effects*		*Long-term – systemic effects*		*Long-term – local effects*	
dermal (mg/kg bw /day)	Inhalation (mg/m3)	Dermal (mg/cm2)	Inhalation (mg/m3)	Dermal (mg/kg bw /day)	Inhalation (mg/m3)	Dermal (mg/cm2)	Inhalation (ppm)
n.a.	n.a.	n.a.	n.a.	42	25.7	n.a.	n.a.

n.a. = not applicable

Table 10.3 DN(M)ELs for General Population

Acute – systemic effects			*Acute – local effects*		*Long-term – systemic effects*			*Long-term – local effects*	
Dermal (mg/kg bw /day)	Inhalation (mg/m3/ day)	Oral (mg/kg bw/day)	Dermal (mg/cm2)	Inhalation (mg/m3)	Dermal (mg/kg bw /day)	Inhalation (mg/kg bw/day)	Oral (mg/kg bw /day)	Dermal (mg/cm2)	Inhalation (mg/m3)
n.a.	n.a.	n.a.	n.a.	n.a.	21	n.a.	3.65	n.a.	n.a.

n.a. = not applicable

10.1. Exposure scenario 1: Use as an intermediate

10.1.1. Human health

10.1.1.1. Workers

Identifier *	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES1-W1	General exposures [CS1]. ; Continuous process [CS54]. ; (closed systems) [CS107]	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES1-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES1-W3	Use in contained batch processes [CS37].	0.74	0.01	0.75	n.a.	n.a.	n.a.
ES1-W4	General exposures (open systems) [CS16].	0.12	0.16	0.29	n.a.	n.a.	n.a.
ES1-W5	Process sampling [CS2]. ; (closed systems) [CS107]	0.25	0.01	0.25	n.a.	n.a.	n.a.
ES1-W6a	Equipment cleaning and maintenance [CS39].	0.35	0.33	0.67	n.a.	n.a.	n.a.
ES1-W6b	Equipment cleaning and maintenance [CS39].	0.25	0.33	0.57	n.a.	n.a.	n.a.
ES1-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]	0.52	0.16	0.68	n.a.	n.a.	n.a.
ES1-W8	Bulk product storage [CS85]; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES1-W9	Laboratory activities [CS36].	0.86	0.01	0.87	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.1.1.2. Consumers

Not applicable

10.1.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.1.2. Environment

Compartments: Risk Characterization Ratio	*ES1-E1*
STP	1.64E-05
Freshwater	1.79E-04
Freshwater sediment	1.77E-04
Soil	2.56E-06
Marine water	1.77E-04
Marine water sediment	1.75E-04

10.2. Exposure scenario 2: Use as a process solvent

10.2.1. Human health

10.2.1.1. Workers

Identifier *	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES2-W1	General exposures [CS1]. ; Continuous process [CS54]. ; (closed systems) [CS107]	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES2-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES2-W3	Use in contained batch processes [CS37].	0.74	0.01	0.75	n.a.	n.a.	n.a.
ES2-W4	General exposures (open systems) [CS16].	0.12	0.16	0.29	n.a.	n.a.	n.a.
ES2-W5	Process sampling [CS2]. ; (closed systems) [CS107]	0.25	0.01	0.25	n.a.	n.a.	n.a.
ES2-W6a	Equipment cleaning and maintenance [CS39].	0.35	0.33	0.67	n.a.	n.a.	n.a.
ES2-W6b	Equipment cleaning and maintenance [CS39].	0.25	0.33	0.57	n.a.	n.a.	n.a.
ES2-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]	0.52	0.16	0.68	n.a.	n.a.	n.a.
ES2-W8	Bulk product storage [CS85]; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES2-W9	Laboratory activities [CS36].	0.86	0.01	0.87	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.2.1.2. Consumers

Not applicable

10.2.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.2.2. Environment

Compartments: Risk Characterization Ratio	*ES2-E1*
STP	9.10E-06
Freshwater	1.07E-04
Freshwater sediment	1.05E-04
Soil	1.44E-06
Marine water	1.04E-04
Marine water sediment	1.03E-04

10.3. Exposure scenario 3: Distribution

10.3.1. Human health

10.3.1.1. Workers

Identifier *	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES3-W1	General exposures (closed systems) [CS15]. ; Continuous process [CS54]. ; No sampling [CS57].	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES3-W2	General exposures (closed systems) [CS15]. ; Continuous process [CS54]. ; With sample collection [CS56].	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES3-W3	General exposures [CS1]. ; Use in contained batch processes [CS37]. ; With sample collection [CS56].	0.74	0.01	0.75	n.a.	n.a.	n.a.
ES3-W4	General exposures (open systems) [CS16].	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES3-W5	Process sampling [CS2]. ; (closed systems) [CS107]	0.25	0.01	0.25	n.a.	n.a.	n.a.
ES3-W6	Bulk transfers [CS14]. ; Dedicated facility [CS81]; (closed systems) [CS107]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES3-W7	Bulk transfers [CS14]. ; Dedicated facility [CS81]; (open systems) [CS108]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES3-W8	Drum/batch transfers [CS8]. ; Dedicated facility [CS81]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES3-W9	Drum and small package filling [CS6]. ; Dedicated facility [CS81]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES3-W10a	Equipment cleaning and maintenance [CS39].	0.49	0.07	0.56	n.a.	n.a.	n.a.
ES3-W10b	Equipment cleaning and maintenance [CS39].	0.25	0.07	0.31	n.a.	n.a.	n.a.
ES3-W11	Bulk product storage [CS85]; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES3-W12	Laboratory activities [CS36].	0.86	0.01	0.87	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.3.1.2. Consumers

Not applicable

10.3.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

Compartments: Risk Characterization Ratio	*ES3 -E1*
STP	1.27E-07
Freshwater	1.68E-05
Freshwater sediment	1.66E-05
Soil	5.33E-08
Marine water	1.44E-05
Marine water sediment	1.42E-05

10.4. Exposure scenario 4: Formulation and (re)packing of substances and mixtures

10.4.1. Human health

10.4.1.1. Workers

Identifier	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES4-W1	General exposures [CS1]. ; Continuous process [CS54]. ; No sampling [CS57]. ; (closed systems) [CS107]	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES4-W2	General exposures [CS1]. ; Continuous process [CS54]. ; With sample collection [CS56]. ; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES4-W3	General exposures [CS1]. ; Use in contained batch processes [CS37]. ; With sample collection [CS56].	0.74	0.01	0.75	n.a.	n.a.	n.a.
ES4-W4	General exposures (open systems) [CS16].	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES4-W5	Process sampling [CS2]. ; (closed systems) [CS107]	0.25	0.01	0.25	n.a.	n.a.	n.a.
ES4-W6	Bulk transfers [CS14]. ; Dedicated facility [CS81]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES4-W7	Mixing operations (open systems) [CS30].	0.86	0.07	0.93	n.a.	n.a.	n.a.
ES4-W8	Transfer from/pouring from containers [CS22]. ; Manual [CS34].	0.49	0.33	0.82	n.a.	n.a.	n.a.
ES4-W9	Drum/batch transfers [CS8]. ; Dedicated facility [CS81]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES4-W10	Production or preparation or articles by tabletting, compression, extrusion or pelletisation [CS100]	0.86	0.08	0.95	n.a.	n.a.	n.a.
ES4-W11	Drum and small package filling [CS6]. ; Dedicated facility [CS81]	0.86	0.03	0.90	n.a.	n.a.	n.a.
ES4-W12a	Equipment cleaning and maintenance [CS39].	0.49	0.07	0.56	n.a.	n.a.	n.a.
ES4-W12b	Equipment cleaning and maintenance [CS39].	0.25	0.07	0.31	n.a.	n.a.	n.a.
ES4-W13	Bulk product storage [CS85]; (closed systems) [CS107]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES4-W14	Laboratory activities [CS36].	0.86	0.01	0.87	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.4.1.2. Consumers

Not applicable

10.4.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.4.2. Environment

Compartments: Risk Characterization Ratio	*ES4-E1*
STP	0.0013
Freshwater	0.0127
Freshwater sediment	0.0125
Soil	0.0014
Marine water	0.0127
Marine water sediment	0.0125

10.5. Exposure scenario 5: Industrial use in coatings (water based)

10.5.1. Human health

10.5.1.1. Workers

Identifier *	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES5-W1	General exposures (closed systems) [CS15].	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES5-W2	General exposures (closed systems) [CS15]. ; With sample collection [CS56].	0.07	0.03	0.11	n.a.	n.a.	n.a.
ES5-W3	Film formation - force drying (50 - 100°C). Stoving (>100°C). UV/EB radiation curing [CS94].	0.74	0.03	0.77	n.a.	n.a.	n.a.
ES5-W4	Mixing operations (closed systems) [CS29]. ; General exposures (closed systems) [CS15].	0.22	0.01	0.23	n.a.	n.a.	n.a.
ES5-W5	Film formation - air drying [CS95].	0.37	0.16	0.53	n.a.	n.a.	n.a.
ES5-W6	Preparation of material for application [CS96]. ; Mixing operations (open systems) [CS30].	0.37	0.33	0.70	n.a.	n.a.	n.a.
ES5-W7	Spraying (automatic/robotic) [CS97].	0.37	0.05	0.42	n.a.	n.a.	n.a.
ES5-W8	Spraying [CS10]. ; Manual [CS34].	0.74	0.20	0.94	n.a.	n.a.	n.a.
ES5-W9	Material transfers [CS3]. ; Non-dedicated facility [CS82]	0.74	0.07	0.81	n.a.	n.a.	n.a.
ES5-W10	Material transfers [CS3]. ; Dedicated facility [CS81]	0.37	0.16	0.53	n.a.	n.a.	n.a.
ES5-W11	Material transfers [CS3]. ; Drum/batch transfers [CS8]. ; Transfer from/pouring from containers [CS22]. ; Dedicated facility [CS81]	0.37	0.16	0.53	n.a.	n.a.	n.a.
ES5-W12	Roller, spreader, flow application [CS98].	0.74	0.13	0.87	n.a.	n.a.	n.a.
ES5-W13	Dipping, immersion and pouring [CS4].	0.74	0.07	0.81	n.a.	n.a.	n.a.
ES5-W14	Laboratory activities [CS36].	0.37	0.01	0.38	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.5.1.2. Consumers

Not applicable.

10.5.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.5.2. Environment

Compartments: Risk Characterization Ratio	*ES5-E1*
STP	0.0127
Freshwater	0.0133
Freshwater sediment	0.0131
Soil	0.0016
Marine water	0.0133
Marine water sediment	0.0131

10.6. Exposure scenario 6: Professional use in coatings (solvent based)

10.6.1. Human health

10.6.1.1. Workers

Identifier	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES6-W1	General exposures (closed systems) [CS15].	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES6-W2	Filling / preparation of equipment from drums or containers. [CS45].	0.37	0.03	0.40	n.a.	n.a.	n.a.
ES6-W3	General exposures (closed systems) [CS15]. ; Use in contained systems [CS38].	0.37	0.03	0.40	n.a.	n.a.	n.a.
ES6-W4	Preparation of material for application [CS96]	0.22	0.01	0.23	n.a.	n.a.	n.a.
ES6-W5	Film formation - air drying [CS95]. ; Outdoor [OC9]	0.74	0.16	0.90	n.a.	n.a.	n.a.
ES6-W6	Film formation - air drying [CS95]; Indoor [OC8]	0.74	0.16	0.90	n.a.	n.a.	n.a.
ES6-W7	Preparation of material for application [CS96]; Indoor [OC8]	0.74	0.07	0.81	n.a.	n.a.	n.a.
ES6-W8	Preparation of material for application [CS96]; Outdoor [OC9]	0.74	0.07	0.81	n.a.	n.a.	n.a.
ES6-W9	Material transfers [CS3]. ; Drum/batch transfers [CS8]. ; Non-dedicated facility [CS82]	0.74	0.07	0.81	n.a.	n.a.	n.a.
ES6-W10	Material transfers [CS3]. ; Dedicated facility [CS81]; Drum/batch transfers [CS8].	0.74	0.16	0.90	n.a.	n.a.	n.a.
ES6-W11	Roller, spreader, flow application [CS98]. ; Indoor [OC8]	0.74	0.13	0.87	n.a.	n.a.	n.a.
ES6-W12	Roller, spreader, flow application [CS98]; Outdoor [OC9]	0.74	0.13	0.87	n.a.	n.a.	n.a.
ES6-W13	Spraying [CS10]. ; Manual [CS34]. ; Outdoor [OC9]	0.74	0.13	0.87	n.a.	n.a.	n.a.
ES6-W14	Spraying [CS10]. ; Manual [CS34]. ; Intdoor [OC8]	0.89	0.05	0.94	n.a.	n.a.	n.a.
ES6-W15	Dipping, immersion and pouring [CS4]. ;	0.74	0.07	0.81	n.a.	n.a.	n.a.

	Indoor [OC8]						
ES6-W16	Dipping, immersion and pouring [CS4]. ; Outdoor [OC9]	0.74	0.07	0.81	n.a.	n.a.	n.a.
ES6-W17	Laboratory activities [CS36].	0.74	0.01	0.75	n.a.	n.a.	n.a.
ES6-W18	Hand application - fingerpaints, pastels, adhesives [CS72]; Indoor [OC8]	0.74	0.17	0.91	n.a.	n.a.	n.a.
ES6-W19	Hand application - fingerpaints, pastels, adhesives [CS72]; Outdoor [OC9]	0.74	0.17	0.91	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.6.1.2. Consumers

Not applicable.

10.6.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.6.2. Environment

Compartments: Risk Characterization Ratio	*ES6-E1*
STP	3.99E-08
Freshwater	1.59E-05
Freshwater sediment	1.58E-05
Soil	3.44E-08
Marine water	1.35E-05
Marine water sediment	1.34E-05

10.7. Exposure scenario 7: Consumer use in coatings (water based)

10.7.1. Human health

10.7.1.1. Workers

Not applicable.

10.7.1.2. Consumers

The table below summarizes the risk characterisatio n for the water based paint product. The refined analysis for paint brush or roller application scenario had a combined RCR of 0.30 and it was considered acceptable because the RCR was less than 1.

Identifier	*Product or article (sub) categories*	*Risk Characterization Ratio Long term*				*Risk Characterization Ratio Acute*			
		Dermal	*Oral*	*Inhal.**	*Combined routes*	*Dermal*	*Oral*	*Inhal.*	*Combined routes*
ES7-C1	Water borne paints default analysis	0.13	n.a.	0.005	0.14	n.a.	n.a.	n.a.	n.a.
ES7-C2	Water borne paints refined analysis	0.29	n.a.	0.013	0.30	n.a.	n.a.	n.a.	n.a.

* Inhalation RCR used oral DNEL because there is no inhalation DNEL.

10.7.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.7.2. Environment

Compartments: Risk Characterization Ratio	*ES7-E1*
STP	1.06E-07
Freshwater	1.16E-05
Freshwater sediment	1.14E-05
Soil	3.46E-08
Marine water	1.35E-05
Marine water sediment	1.33E-05

10.8. Exposure scenario 8: Professional use in cleaning agents

10.8.1. Human health

10.8.1.1. Workers

Identifier	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES8-W1	Filling / preparation of equipment from drums or containers. [CS45]. ; Dedicated facility [CS81]	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES8-W2	General exposures (closed systems) [CS15].	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES8-W3	Use in contained systems [CS38]. ; Automated process with (semi) closed systems [CS93]	0.12	0.03	0.16	n.a.	n.a.	n.a.
ES8-W4	Use in contained systems [CS38]. ; Automated process with (semi) closed systems [CS93]; Drum/batch transfers [CS8].	0.07	0.01	0.08	n.a.	n.a.	n.a.
ES8-W5	Semi Automated process. (e.g.: Semi automatic application of floor care and maintenance products) [CS76]	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES8-W6	Filling / preparation of equipment from drums or containers. [CS45]. ; Non-dedicated facility [CS82]; Outdoor [OC9]	0.62	0.33	0.94	n.a.	n.a.	n.a.
ES8-W7	Cleaning [CS47]. ; Surfaces [CS48]. ; Manual [CS34]. ; Dipping, immersion and pouring [CS4].	0.25	0.33	0.57	n.a.	n.a.	n.a.
ES8-W8	Cleaning with low-pressure washers [CS42].	0.62	0.13	0.75	n.a.	n.a.	n.a.
ES8-W9	Cleaning [CS47]. ; Surfaces [CS48]. ; Manual [CS34]. ; Spraying [CS10].	0.62	0.13	0.75	n.a.	n.a.	n.a.
ES8-W10	Ad hoc manual application via trigger sprays, dipping, etc. [CS27]. ; Rolling, Brushing [CS51].	0.62	0.13	0.75	n.a.	n.a.	n.a.
ES8-W11	Ad hoc manual application via trigger sprays, dipping, etc. [CS27]. ; Rolling, Brushing [CS51].	0.62	0.13	0.75	n.a.	n.a.	n.a.
ES8-W12	Application of cleaning products in closed systems [CS101]	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES8-W13	Cleaning of medical devices [CS74]	0.25	0.16	0.41	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.8.1.2. Consumers

Not applicable.

10.8.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.8.2. Environment

Compartments: Risk Characterization Ratio	*ES8-E1*
STP	2.74E-11
Freshwater	1.55E-05
Freshwater sediment	1.54E-05
Soil	3.03E-08
Marine water	1.31E-05
Marine water sediment	1.30E-05

10.9. Exposure scenario 9: Consumer use in cleaning agents

10.9.1. Human health

10.9.1.1. Workers

Not applicable.

10.9.1.2. Consumers

The table below summarizes the risk characterisation for the cleaning product. The hard surface cleaner spraying and wiping scenarios had a RCR for the combined routes of 0.02 and it was considered acceptable because the RCR was less than 1.

The floor cleaner mixing and application scenarios had a combined RCR of 0.76 and it was considered acceptable because the RCR was less than 1.

Identifier	*Product or article (sub) categories*	*Risk Characterization Ratio Long term*				*Risk Characterization Ratio Acute*			
		Dermal	*Oral*	*Inhal.**	*Combined routes*	*Dermal*	*Oral*	*Inhal.*	*Combined routes*
ES9-C1	Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) hard surface cleaner spraying and wiping.	0.02	0.0003	0.002	0.02	n.a.	n.a.	n.a.	n.a.
ES9-C2	Floor cleaning liquid including mixing & loading and application.	0.75	n.a.	0.005	0.76	n.a.	n.a.	n.a.	n.a.

* Inhalation RCR used oral DNEL because there is no inhalation DNEL.

10.9.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.9.2. Environment

Compartments: Risk Characterization Ratio	*ES9-E1*
STP	6.86E-07
Freshwater	2.24E-05
Freshwater sediment	2.21E-05
Soil	1.00E-07
Marine water	2.00E-05
Marine water sediment	1.98E-05

10.10. Exposure scenario 10: Professional use in metal working fluids/rolling oils

10.10.1. Human health

10.10.1.1. Workers

*Identifier**	*Contributing scenarios*	*Risk Characterization Ratio Long term*			*Risk Characterization Ratio Acute*		
		Inhalation	*Dermal*	*Combined routes*	*Inhalation*	*Dermal*	*Combined routes*
ES10-W1	General exposures (closed systems) [CS15].	0.00	0.01	0.01	n.a.	n.a.	n.a.
ES10-W2	General exposures (closed systems) [CS15]. ; Batch process [CS55].	0.07	0.01	0.08	n.a.	n.a.	n.a.
ES10-W3	General exposures (open systems) [CS16]. ; Batch process [CS55].	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES10-W4	General exposures (closed systems) [CS15]. ; With sample collection [CS56].	0.12	0.03	0.16	n.a.	n.a.	n.a.
ES10-W5	Material transfers [CS3]. ; Dedicated facility [CS81]	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES10-W6	Filling / preparation of equipment from drums or containers. [CS45].	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES10-W7	Filling / preparation of equipment from drums or containers. [CS45].	0.25	0.16	0.41	n.a.	n.a.	n.a.
ES10-W8	Process sampling [CS2].	0.07	0.01	0.08	n.a.	n.a.	n.a.
ES10-W9	Metal machining operations [CS79]	0.25	0.03	0.28	n.a.	n.a.	n.a.
ES10-W10	Metal machining operations [CS79]; with potential for aerosol generation [CS138]	0.04	n.a.	n.a.	n.a.	n.a.	n.a.
ES10-W11	Treatment by dipping and pouring [CS35].	0.25	0.33	0.57	n.a.	n.a.	n.a.
ES10-W12	Spraying [CS10].	0.25	0.51	0.76	n.a.	n.a.	n.a.
ES10-W13	Roller, spreader, flow application [CS98].	0.62	0.13	0.75	n.a.	n.a.	n.a.
ES10-W14	Equipment cleaning and maintenance [CS39].	0.62	0.33	0.94	n.a.	n.a.	n.a.
ES10-W15	Storage [CS67]; (closed systems) [CS107]	0.12	0.03	0.16	n.a.	n.a.	n.a.

*Identifier: each product or article (sub) category of the ES has been assigned a unique identifier which facilitates tracking all the information (exposure estimation, risk characterization in chapter 9 and 10 and appendices) related to this product or article (sub) category of the ES.

10.10.1.2. Consumers

Not applicable.

10.10.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.10.2. Environment

Compartments: Risk Characterization Ratio	*ES10-E1*
STP	2.63E-06
Freshwater	4.19E-05
Freshwater sediment	4.14E-05
Soil	2.99E-07
Marine water	3.95E-05
Marine water sediment	3.90E-05

10.11. Exposure scenario 11: Use in cosmetics (environment)

10.11.1. Human health

10.11.1.1. Workers

Not applicable.

10.11.1.2. Consumers

Not applicable.

10.11.1.3. Indirect exposure of humans via the environment

PPh is expected to have a low bioaccumulation potential so it is not expected that there is a significant exposure for humans or predators via the local environment. Moreover as PPh is not classified as very toxic (T+), toxic (T), or harmful (Xn and R48) it is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore exposure of humans via the environment can be considered negligible.

10.11.2. Environment

Compartments: Risk Characterization Ratio	*ES10-E1*
STP	3.12E-07
Freshwater	1.87E-05
Freshwater sediment	1.84E-05
Soil	6.22E-08
Marine water	1.63E-05
Marine water sediment	1.61E-05

10.12 Overall exposure (combined for all relevant emission/release sources)

10.12.1. Human health (combined for all exposure routes)

The combined exposure was evaluated for the potential use of two consumer products on the same day. Consumers frequently use cleaners; tile sealers are used infrequently, printer cartridges are changed infrequently, and paints are used infrequently. The combined exposure assumed a hard surface cleaner (ES9-C1) was used on the same day as the floor cleaner product (ES9-C2). The combined RCR was 0.78 on the day of exposure for use of the hard surface cleaner (RCR = 0.02) and the floor cleaner (RCR = 0.76). This combined exposure was acceptable because the combined RCR was less than 1.
For indirect exposure of humans via the environment, PPh is expected to have a low bioaccumulation potential. The bioconcentration factor for fish is very low so it is not expected that there is a significant exposure for humans or predators via the local environment. It is assumed that there is a low potential for the substance to cause toxic effects if accumulated in higher organisms, therefore secondary poisoning can be considered negligible.
The combined exposure of use of a consumer product by a worker at home has not been quantitatively evaluated. The contribution of the inhalation and dermal exposure due to the use of the consumer product on a yearly basis is negligible compared to the daily inhalation and dermal occupational exposure (8 hour working day).

10.12.2. Environment (combined for all emission sources)

Compartments: (REGIONAL)	*RCR*
Freshwater	1.55E-05
Marine water	1.31E-05
Freshwater sediment	1.31E-05
Marine water sediment	1.12E-05
Soil	1.08E-05

10.13. Qualitative assessment of risks from eye irritation

For eye irritation a qualitative risk characterisation was conducted. Handling and storage risk management measures that are generally identified for eye irritation are given in the table below.

Hazard	Material	Risk/ Hazard phrase	Examples of relevant Precautionary (P) Statements and Safety (S) Phrases	Components of the Qualitative Risk Assessment
Eye irritation	Liquid	R36/ H319	• P264: Wash with water thoroughly after handling. • P280: Wear protective gloves/protective clothing/eye protection/face protection. • S25: Avoid contact with eyes • S39: Wear eye/face protection • P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. • P337 + P313: If eye irritation persists: Get medical advice/attention. • S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice	• Implementation of basic standards of occupational hygiene; • Avoid direct contact with product; • Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately; • Wear protective gloves and suitable eye protection at all times when handling the substance • Avoid splashes and spills; • Avoidance of contact with contaminated tools and objects; • Clean up contamination/spills as soon as they occur; • Regular cleaning of equipment and work area; • Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed; • Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop; • Adopt good standards of personal hygiene. • Where activities may lead to aerosol release e.g. spraying, then additional skin and eye protection measures such as impervious suits and face shields may be required.

A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye irritation can considered to be adequately controlled.

- [PPE26]: Use suitable eye protection.
- [E73]: Avoid direct eye contact with product, also via contamination on hands.

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